REPORT OF THE SUB-COMMITTEE
ON INSTITUTIONAL PROGRAM GUIDELINES

GUIDELINES FOR ESTABLISHING STANDARDS
FOR SPECIAL SERVICES IN HOSPITALS

CARDIOVASCULAR SERVICES IN HOSPITALS

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IMPORTANT

The information contained in these guidelines was current at the time of publication. It should be remembered that certain aspects of the delivery of health care and health technology are changing rapidly. Should you identify any out-of-date material in the text, please inform:

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GENERAL INTRODUCTION

Background

Advances in health technology and changes in the planning and delivery of health care have contributed to an increasing demand for specialized care facilities and services in hospitals. A dramatic rise in the number of intensive and specialized care facilities and services in hospitals has occurred in recent decades due to rapid technological development in electronics and automation, and as a result of new approaches to patient care. These changes have produced demands for physical facilities, specialized equipment and highly-trained health manpower. Because of this, there is a continuing need for guidelines for standards to assist those involved in planning, organizing and operating special care services in hospitals.

Mandate

In 1972 health authorities in Canada recognized the need for guidance in this area, and the Federal-Provincial Advisory Committee on Health Insurance commissioned the Working Group on Special Services in Hospitals to create guidelines for standards to provide a reliable definition of requirements for a number of special care facilities and services.

Guidelines were developed by the working group for 14 units and services, and, in 1975, these were published under the title, "Guidelines for Special Care Units in Hospitals". This volume was widely distributed to provincial health and hospital authorities, and to national and international health organizations, and has been adopted by many as a guide.

The continuing development of existing and new health technologies, together with changes occurring in the pattern of health care delivery, gave impetus to the updating of the 1975 guidelines, and to the

development of guidelines in additional areas. In May 1982, the Federal-Provincial Advisory Committee on Institutional and Medical Services granted the working group continuing status as a sub-committee of the advisory committee, called the Sub-Committee on Special Services in Hospitals. With the continued broadening of the scope of the work, in 1985 the name was again changed to the Sub-Committee on Institutional Program Guidelines. A complete list of guidelines published or being prepared by the sub-committee is appended.

Methodology

The guidelines published in 1975 were developed on the principle of a consensus of information, knowledge, experience and expert opinion obtained from appropriate organizations and individuals throughout Canada. They were based, where possible, on guidelines developed in Canada, and from authoritative sources in other countries. This approach has been generally acceptable to government and hospital authorities and the health professions.

The present guidelines were prepared on a similar basis. On this occasion, in addition to input from provincial authorities, the expert opinion of health professionals was obtained through formally designated representatives of national health organizations representing the activities involved in each specific service. It is certain that many hundreds of health professionals from every area of the country have provided expert input in these guidelines by this method, and have thus provided a truly Canadian consensus on these topics.

Suggested purpose of the guidelines

The guidelines should not be regarded as rigid standards. Their application may vary throughout Canada, and it is the prerogative of each province to accept, modify or reject the guidelines according to provincial priorities.

The purpose of the guidelines is to provide a definition of requirements for a number of special care facilities and services. They are not intended to provide standards for clinical practice.

Where development of a unit is under consideration, the guidelines will assist planners and government health authorities in determining the need for such a unit, and in assessing the total potential impact of a new unit on existing and projected services, both at the local and regional levels. Deficiencies in existing services can be identified, and in some cases these can be corrected without the need to develop a new unit.

Where a unit already exists in a hospital, the guidelines will help to identify problem areas related to administration, personnel, equipment, and physical facilities. They will help to determine necessary remedial action and to set priorities for corrective measures on the basis of clinical need, fiscal realities, and the degree to which a deficiency in the physical facilities impedes adequate functioning of the unit.

Future revisions

Because of the rapidly changing nature of health care, the guidelines will require regular revision. It is planned to maintain the sub-committee to carry out this function.

Acknowledgments

The sub-committee acknowledges with sincere appreciation the immense amount of work undertaken and time given by practising health professionals in Canada in providing detailed written information and guidance in the preparation of these guidelines. In addition, we wish to thank the many others who, in any way contributed advice and information to this endeavour.

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1. INTRODUCTION

CARDIOVASCULAR SERVICES IN HOSPITALS

I INTRODUCTION

> "Cardiovascular services and units are those which are designed, staffed and equipped to provide for the investigation, medical/surgical treatment, and/or rehabilitation of patients with proven or suspected disease(s) of the heart, arteries, veins, lymphatic vessels and microcirculation (arterioles, capillaries and venules). With the exception of certain techniques for the investigation of carotid artery disease (as described in the guidelines for vascular laboratories) the cerebrovascular system is not included in this section."

The term "service" or "unit" is used in the guidelines where appropriate. For the sake of brevity the term "C V services" is used to cover both units and services in the remainder of the introduction.

These are "programs" guidelines not "clinical" guidelines. However, as should be evident throughout, clinical performance and results - as well as cost effectiveness - may be significantly influenced by such factors as patient load, staffing, equipment and physical plant design.

It is the purpose of these guidelines to provide current essential information that will assist those involved in the planning, organization and operation of cardiovascular services.

Although all of the C V services addressed in the guidelines are hospital-based or hospital-related, decisions regarding their development and expansion should be made on the basis of community, regional and provincial needs and resources. This consideration may also apply to "updating" where this results in significant alteration in the case load capabilities of a given service.

General considerations regarding C V services may be outlined under nine headings:

1. Need and Demand

- All Canadians regardless of age, sex, racial/ethnic origin, or geographic location are at risk of developing some form of cardiovascular disease.

- For most, the history and physical examination as performed by a physician, supplemented where indicated by an ECG, routine radiographic procedures, and biochemical tests are all that are required for identification of patients at high risk or for establishing a diagnosis of cardiovascular disease. It should be noted that nurses may "identify" patients at risk while taking nursing histories and bring them to the attention of physicians.

- For some, the results of the above tests will indicate that consultation and/or more elaborate forms of investigation or treatment will be required - i.e. the cardiovascular services described in these guidelines.

- The need for cardiovascular services may arise on an emergency or on an elective basis. In both instances, availability and accessability are major concerns and require consideration of demographic, geographic and climatic factors.

- A large number of Canadians live in rural or small urban areas where few or no highly specialized C V services exist. In general, the total range of C V services is usually available only in a large city with a medical school and affiliated teaching hospitals. Even then, such highly subspecialized activities as pediatric cardiac surgery may be unavailable or limited in scope. This means that most Canadians must travel to obtain certain C V services. This may be between hospitals in the same or different communities, or to hospitals in other regions or outside the

province. The smaller the community, and the more sophisticated the service, the more likely that the patient will have to travel to obtain the required service.

- An unacceptably low patient load for a given service may result from geographic location or by unnecessary duplication of the service within a given area. This emphasizes that all C V services must be considered within the context of the needs and resources of the community, region and province.

- The fact that most patients must be referred imposes two major responsibilities on those using or providing C V services:

(a) Transportation: this may be required between hospitals in the same or different cities. Depending on the clinical and social circumstances, this may entail supervision, special modes of transportation and costs for these requirements.

(b) Two-way communication between the referring physician and the service providers: clinical data and recommendations must be made available within the time required for investigation and follow-up of the patient. The logistical support required by the service in meeting this obligation must not be neglected.

2. Cardiovascular Diseases

- There are many different cardiovascular diseases. Some are congenital, becoming clinically evident any time from birth through adult life. The majority of C V diseases are acquired and are either non-ischemic or ischemic. Ischemic heart disease is by far the most common form of acquired heart disease. In over 95 per cent of cases, ischemic heart disease is due to atherosclerosis of the coronary arteries - a process which begins in childhood and becomes a

statisically significant cause of death and morbidity in men by age 35 and in women by age 45 years. Ischemic heart disease accounts for over two-thirds of the total case load of all patients investigated and treated for congenital and acquired heart disease.

- Because of the frequency with which ischemic heart disease presents as sudden death (of those who die of ischemic heart disease, sudden death is the first clinical manifestation of the disease in approximately 25 per cent to 30 per cent), identification of the individual at risk is of major importance.

- The pathophysiological characteristics of acute ischemic heart disease require early surveillance and intervention, hence the need for emergency cardiac care, Cardiac Care Units and Intensive Care Units. In addition, the development of therapies which are most effective early in the history of cardiac disease lends further weight to the emphasis on early detection.

- Acquired diseases of the arteries, veins and microcirculation of the upper and lower extremities represent major causes of discomfort and disability. Their incidence and prevalence become significant as early as the third decade, and thereafter increase steadily with age. Non-invasive vascular laboratories are used for the purposes listed under C.V. Investigation below.

3. Prevention

Currently available preventive measures have effected a major reduction in the morbidity and mortality associated with a number of cardiovascular diseases. Cardiovascular services provide the means and the setting for secondary and tertiary preventive measures. For example, non-invasive techniques may be required to identify the individual at high risk of sudden death. Cardiovascular services also provide the opportunity for influencing effective primary prevention.

Atherosclerosis is responsible for the major workload of cardiovascular services. To date, primary prevention of atherosclerosis remains an unsolved problem requiring continued intensive research. On the other hand, secondary and tertiary prevention has been made possible, to a large extent, by investigation and management methods provided by cardiovascular services. In addition, the need for on-going evaluation of specific activities within the three levels of prevention will continue to require the use of non-invasive techniques to an increasing degree.

Based on the above, and without detracting from the value of prevention as it now exists, the expectation that effective promotion of an improved lifestyle will be attended by a sharp reduction in the need for cardiovascular services is unwarranted. Until primary prevention of Atherosclerosis has been achieved, there is unlikely to be a decrease in the need for therapeutic cardiovascular services. Furthermore, increased emphasis on prevention will be attended by an increased demand for non-invasive procedures.

4. C V Investigation

(a) Indications for one or more C V services include the following:

- Under special circumstances, to detect evidence of disease in asymptomatic individuals.

- To determine whether equivocal clinical evidence is due to actual C V disease or to other causes.

- To detect and delineate the disease process anatomically, to establish the etiological diagnosis, to quantitate alterations in function resulting from disease.

- To assist in medical management of the patient.

- To assist in determining if surgical treatment is indicated.

- To assess response to medical or surgical therapy.

- To assess the relative value of different types of therapy.

- Under special circumstances, to assist in determining the prognosis.

- To provide anatomical and physiological data that will assist in guiding the treatment and rehabilitation of the patient.

(b) Cardiac catheterization is the most elaborate and comprehensive form of invasive C V technology. It is a tertiary level service which in Canada is usually located in large referral centres. With the increased acceptance of aortocoronary bypass graft surgery and newer methods of arrhythmia detection and treatment, the demand for cardiac catheterization has increased markedly.

(c) As a result of rapid technological developments, non-invasive C V services, such as echocardiography, occupy an increasingly large role in the evaluation of cardiovascular disease. Non-invasive techniques may be used: (1) to yield information not available with invasive techniques; (2) to supplement information obtained by invasive techniques, or (3) to replace certain invasive techniques by providing similar information more quickly and with less risk.

5. Emergency Cardiac Care

For patients with acute ischemic heart disease, immediate and long-term survival, as well as morbidity, can be favourably influenced by an effective community-based program of emergency cardiac care (ECC). For this reason, ECC is now recognized as

an essential component of the spectrum of services required for effective management of patients with acute ischemic heart disease and other acute life-threatening cardiovascular and pulmonary problems.[1]

6. Cardiac Care Units and Intermediate Cardiac Care Units

The role of the Cardiac Care Unit is changing. Hemodynamic monitoring has been added to arrhythmia monitoring to permit more intensive pharmacologic therapy and more precise assessment of selected patients.

Both the Cardiac Care Unit and the Intermediate Cardiac Care Unit are becoming increasingly dependent on non-invasive C V services - a trend that is likely to continue.

The role of the Intermediate Cardiac Care Unit is evolving with particular emphasis on patient activation and rehabilitation, as well as telemetric monitoring.

7. Cardiac Surgery

The current acceptance of surgery in the treatment of coronary heart disease and its complications has resulted in a phenomenal increase in the demand for cardiac surgery. Aortocoronary bypass graft surgery now accounts for over two-thirds of all cardiac surgery performed in Canada. A similarly important role may ultimately be assumed by percutaneous transluminal coronary angioplasty, but its likely impact on cardiac surgery is not yet defined.

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[1] See guidelines for Emergency Services in Hospitals 1981 and Prehospital Emergency Care, 1985 Subcommittee on Institutional Program Guidelines, Health Services Directorate. Department of National Health and Welfare.

Cardiac transplants are likely to be accepted as part of the treatment alternatives for end-stage cardiac disease in the near future.[2]

This growing public and professional acceptance of surgery as a proven method of dealing with coronary heart disease has contributed to the dramatic increase in demand for invasive and certain non-invasive investigations.

8. Cardiac Rehabilitation

All C V investigation and treatment is of limited value if, in the end, the patient is not restored to a reasonable level of physical, mental and social well-being. Cardiac rehabilitation is required whenever C V disease affects the patient's activity and productivity. It should be continued as long as there is the possibility of improvement. Non-invasive services, particularly ECG stress testing, have become increasingly important in guiding rehabilitation.

9. Impact on Other Services

As institutions become more involved in cardio-vascular services, other departments will be directly impacted, including:

1. Anesthesia, for more sophisticated procedures;
2. Biomedical engineering, with more complex equipment to acquire and maintain;
3. Laboratory services, particularly for surgical pathology, immunology, cytology, electron microscopy, together with greatly increased workloads in biochemistry, hematology, and microbiology;
4. Pharmacy;
5. Psychology and counselling services;

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[2] A separate guideline for Vital Organ Transplantation Centres is being developed.

6. Radiology and other diagnostic imaging services;
7. Social work.

The contribution of and the need to anticipate the impact of increased cardiovascular programs or services must be considered in any planning.

Most cardiovascular services outlined in this guideline include provision for an advisory committee to the director and for audits and other reviews of care quality. It is assumed in all cases that hospital bylaws and protocols include regular peer review and review of privileges for members of the medical staff, as well as audits of quality of care and other current quality assurance requirements of the accreditation standards published by the Canadian Council on Hospital Accreditation.

10. The Potential Value of Comprehensive C V Guidelines

In general, there is a high degree of interdependence between C V services. This requires consideration when guidelines are developed. To date, practical recognition of these essential relationships has been impeded by (a) rapid changes in the various fields, and (b) publications of guidelines from various sources at intervals of several years.

The following guidelines address all cardiovascular services. Brief comments on prevention and emergency cardiac care have been provided above to emphasize a comprehensive approach to cardiovascular disease. It should also be emphasized that this field is still changing rapidly in all of its parameters: investigative procedures, medications, surgical procedures (including transplants); therefore, the guidelines must be updated frequently.

Decisions regarding the development or modification of cardiovascular services will be required with increasing frequency. The quality of these decisions will be directly dependent upon the quality of the

information on which they are based. It is the purpose of the guidelines to provide such information.

II. INVESTIGATION

II INVESTIGATION

A. Non-invasive Cardiovascular Investigations

CARDIAC STRESS TESTING LABORATORIES

PREAMBLE

Stress testing is the use of exercise, according to specific criteria, for the purpose of detecting heart disease or for quantifying cardiorespiratory function. It is not to be confused with exercise testing, which is carried out for the purpose of determining fitness. Such fitness testing is used to formulate individualized exercise programs and is not intended to provide diagnostic or prognostic information. The following guidelines apply to graded multi-staged stress testing.

Stress testing has become an integral part of the evaluation of patients with all forms of heart disease, especially ischemic heart disease. Rapid expansion of knowledge concerning the usefulness of stress testing as an aid to the diagnosis and more recently to the prognosis of patients with coronary heart disease has made it a very useful tool in clinical practice.

The indications or objectives of stress testing are:

- to establish a diagnosis of latent or overt ischemic heart disease by eliciting symptoms of ischemic heart disease or by producing the typical electrocardiographic ST segment response to myocardial ischemia,

- to evaluate the functional or exercise capacity of patients with any form of heart disease, particularly:

  - as a means of determining activity - limiting symptoms
  - as a means of clearing individuals for strenuous work or exercise programs

- as an aid in rehabilitating post-myocardial infarction patients

- to evaluate different forms of cardiac treatment objectively including: exercise programs, antianginal or antiarrhythmic medications and cardiac surgery

- to detect arrhythmias which may be manifest only during exercise

- to detect, in patients with known heart disease, abnormal electrocardiographic, hemodynamic or performance responses which indicate that the patient may be at a higher risk of developing future cardiac events or complications.

Stress testing, especially in patients with known or suspected heart disease, is associated with a small but definite risk. The risk of death during the 24 hours following the stress test and related to stress test is less than 1 in 10 000 tests. There is a very small, but very real, incidence of myocardial infarction, either during the early (one hour) or late (24 hours) phase of the recovery period. The patient is also at risk of developing ventricular tachycardia and/or fibrillation and syncope during the test procedure. It is, therefore, mandatory that the physician responsible for supervising the test be immediately available (within 15 seconds) at all times during the tests and until the patient is considered ready for discharge from the laboratory, and preferably, in actual attendance in the room throughout the procedure. Cardiac resuscitative equipment must be immediately available (in the same room).

Whether or not a particular hospital decides to have a stress testing laboratory as part of their facilities will primarily depend on:

- the number of potential candidates for exercise testing in the community,

- the availability of existing stress testing facilities in the community,

- the availability of physicians to supervise each test.

GUIDELINES

1. PATIENT-LOAD

1.1 Patient Referrals:

Out-patients: are those referred to the laboratory, by physicians in the community, for investigation of chest pain of undetermined origin, suspected ischemic heart disease, known ischemic heart disease and other forms of heart disease.

Hospital In-patients: are those referred to the laboratory for investigation of the same conditions as outpatients and also those patients requiring evaluation of post-infarction conditions before being discharged from hospital.

1.2 Minimum Annual Patient Load:

To justify the expense of acquiring, maintaining and staffing a stress testing laboratory, as well as maintaining the technical competence of staff, a minimum annual case load of 250 cases per year (one patient per working day) is recommended.

2. BED REQUIREMENTS

Active treatment hospital beds are not usually required for the routine stress test. However, under certain circumstances, some patients may require hospitalization and continuous ECG monitoring in the Intensive Care Unit or the Cardiac Care Unit following the stress test. Such circumstances may occur when patients develop a serious arrhythmia, prolonged ischemic chest pain, syncope, myocardial infarction or a suspected myocardial infarction during or after the stress test. It is recommended that hospitals providing stress testing facilities have cardiac monitoring facilities.

3. RECOMMENDED DISTRIBUTION OF STRESS-TESTING LABORATORIES

The minimum recommended number of tests for a laboratory is 250 per year; a major teaching hospital with resident staff can perform up to 2000 tests per year per treadmill or bicycle ergometer (eight tests per working day, one hour per test). It is recommended that the stress-testing facilities be provided in a health district or region with these figures in mind, and that unnecessary duplication of facilities in a community be avoided.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Clinical Direction

A hospital providing an exercise stress-testing facility should designate a physician to direct these services. The laboratory director should be a qualified cardiologist or an internist with a special interest in stress testing. Physicians knowledgeable in stress testing may supervise their own patients during the actual test. However, the laboratory director must have final authority in formulating laboratory policy, patient safety, stress-test procedures and protocol.

4.2 Policies and Procedures

Policies and procedures should be clearly defined in writing and should include statements with respect to:

- the responsibilities of the director of the laboratory;
- the responsibilities of physicians supervising stress tests;
- the responsibilities of technical staff involved in stress testing;

- the requirement for informed consent from each patient prior to stress testing;

- indications for and contraindications to stress testing;

- absolute indications for discontinuing a stress test that is in progress;

- the role of the laboratory staff and hospital personnel when faced with an emergency (e.g. cardiac arrest) in the stress-testing laboratory;

- the provision of continuing care for patients in the unit;

- the disposition of patients requiring hospitalization following a stress test (see Section 2, Bed Requirements);

- the final responsibility for sending official interpretations of the test to the referring physicians and including the interpretations in the patient's hospital chart;

- the frequency of routine safety inspections of laboratory equipment and the procedures performed during the inspections.

4.3 Responsibilities of Staff

Responsibilities of the staff should be clearly defined in writing. In general, it is the responsibility of the:

Laboratory Director: to co-ordinate the overall activity of the laboratory.

Supervising Physicians: to obtain informed consent from the patient for the procedure to be carried out; to be immediately available or present at all times during the test (see Preamble); to co-ordinate emergency procedures, should they arise; to interpret the results of the test.

Technical Staff (technologists): to ensure the patient's understanding of the procedure and his/her comfort and safety; to ensure that the equipment, especially the cardiac defibrillator, is in working order; to monitor the patient's electrocardiogram at all times; to record ECG tracings at appropriate time intervals; and, if delegated by the supervising physician, to obtain informed consent.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Medical Staff

A director of the laboratory: designated by, and responsible to, the hospital and the appropriate Chief of Service.

Supervising medical staff: either the patient's physician, a physician attached to the laboratory, or resident staff when available; all of whom should be knowledgeable in stress testing.

5.2 Technical Staff

There should be at least one technologist available for each procedure performed.

In small laboratories, the technologist may be a member of the ECG Department and only part of his/her time would be spent in attending stress tests. It is important, however, that in such situations the technologists attend enough stress tests each year to maintain a high level of competence (a suggested minimum would be 75 per year).

In larger hospitals, the technologist may be a member of a larger cardiac non-invasive or special cardiac-procedures laboratory and may share the responsibilities of stress testing with other trained technologists in the laboratory, as well as performing other non-invasive tests. Overlapping knowledge and skills obtained in different areas of non-invasive cardiology are often complementary. This makes the

work more interesting, gives the staff greater experience, allows for staff coverage during vacations and sick leave and allows for staff rotation.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

6.1.1 Medical Staff

Laboratory Director

The laboratory director should be a qualified cardiologist or internist with a special interest in stress testing.

Supervising Medical Staff

Supervising medical staff may include the patient's physician or resident staff when available. In either case, the physician should have knowledge of stress testing.

6.1.2 Technical Staff

Technical staff should have basic training as ECG technicians, cardiac technologists or cardiopulmonary technologists. The technologists must have special training in stress testing, and should be certified in Basic Life Support (cardiopulmonary resuscitation). Provincial or national legal certification is recommended.

6.2 Continuing Education

This includes post-graduate courses, conferences, seminars, in-hospital courses, audio visual aids, programmed instruction, visits to special centres and clinical conferences.

6.2.1 Supervising Medical Staff

A minimum of one post-graduate course, conference or convention per year for all supervising staff.

6.2.2 Technical Staff

Technologists associated with a laboratory related exclusively to stress testing will require a minimum of one course, conference or seminar in a related field of interest every two years.

Technologists associated with larger non-invasive laboratories, where procedures other than stress testing are performed and where there is more ongoing peer review, should attend a course, conference, seminar, etc. related to stress testing a minimum of every three years. Such technologists should partake in post-graduate courses every year, but they may be related to non-invasive techniques other than stress testing.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

7.1 Regular Supporting Departments and Services

Biomedical Engineering

Biomedical engineering services are required for routine repairs and maintenance of equipment, as well as for routine safety checks on electromedical equipment.

(Availability of this service from off-site source will suffice.)

Pharmacy

Pharmacy services are required to provide and update drugs used in the cardiac arrest kit.

Porter Service

The transportation of in-patients should be undertaken by persons certified in basic cardiac life support.

7.2 Supporting Departments and Services During a Medical Emergency

In case of a medical emergency in the stress-testing laboratory, the following additional departments and services would be involved: resuscitation team, intensive or cardiac care unit and pharmacy service.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Stress-testing Laboratory

A room should be designated for stress testing. While a test is in progress this room should not be used by personnel other than the supervising physician and attending technologist. The room should be large enough to allow space for a treadmill, monitor and ECG machine and a bed, as well as sufficient space to allow free access to all equipment and for staff to move around freely. A minimum area of 23.22m^2 is recommended.

8.2 Location of Laboratory

When the case load is not large enough to justify setting up a separate non-invasive laboratory, a location should be chosen that is close to the hospital's ECG department, where secretarial, storage and reception facilities, as well as ECG personnel and equipment, can be shared with that department. When the case load is such as to warrant the services of a full-time technologist, or when the stress-testing facilities are a part of a larger non-invasive laboratory, separate facilities for record storage, patient's waiting area and reception are warwarranted. In such a situation, there is no particular advantage for the stress test laboratory to be in proximity to the ECG department.

Since a large out-patient population is usually anticipated, a location easily accessible to the public is desirable.

8.3 Specific Laboratory Requirements

A stress_testing laboratory, regardless of its location in the hospital, has the following specific requirements:

- Dressing room, shower facilities (with an upper-temperature limit for the heat of the water), toilet and lockers for patients.

- Air conditioning to provide a constant ambient temperature of 20-21°C.

- Adequate isolated electrical circuits for treadmill, monitors and defibrillator.

- Oxygen supply, either permanent or portable (cylinders).

9. EQUIPMENT

The basic equipment necessary to perform safe, adequate stress tests includes:

Treadmill

Minimum treadmill belt dimensions 40.65 cm (16 inches) wide by 137.16 cm (54 inches) long.
Speed range: 0 to 16 km/h
Elevation or Grade Range: 0 to 20% elevation.

OR

Bicycle Ergometer

Adjustable load.
Adjustable seat height.

Direct Writing ECG Machine

This machine must meet the American Heart Association's standards for frequency response. The

equipment must be technically capable of providing a tracing during the test as well as before and after the test.

Although a single channel machine is adequate, a three-channel or other multi-channel recorder is highly desirable. It is estimated that an additional 5-8 per cent positive tests are picked up by monitoring in three ECG planes when compared to the conventional single V_5 lead. Three leads allow for easier and more accurate arrhythmia interpretation than a single lead.

Oscilloscope for Continuous Monitoring

One ECG lead must be displayed continuously on the oscilloscope for continuous monitoring of ST segment shifts and for the detection of arrhythmias. This requires an oscilloscope that is specially adapted for use during exercise.

Cardiac Defibrillator

The defibrillator should have synchronous and asychronous modes.

Bed

A bed will be required, preferably with a tilting head, on which to prepare the patient for the test and on which the patient can rest during recovery. A large "lazy boy" type of chair is also satisfactory.

Cardiopulmonary Resuscitation Emergency Kit

The kit should include oral airways, ventilatory equipment, bedboard and the equipment and medication commonly used in cardiopulmonary resuscitation.

Blood Pressure Monitoring Equipment

Blood pressure cuff and stethoscope or other methods of obtaining blood pressure during exercise.

Heart Rate Tachometer

The tachometer should be triggered by the patient's ECG. This allows for immediate and continuous determination of the patient's heart rate.

The following equipment is not essential, but has certain advantages in performing and/or interpreting the results of the test.

Arrhythmia Detecting Computer or ECG monitor Memory Loop

This equipment allows for easier detection and documentation of arrhythmias occurring during exercise.

Metronome

A metronome is useful as an aid for the patient to maintain a particular cycling rate on the bicycle ergometer.

The following options do not change the accuracy or amount of information obtained from the stress test but facilitate the technical aspects of the procedure. They are a definite advantage when large numbers of tests are performed.

Automatic or Programmable Treadmill

The automatic or programmable treadmill automatically increases the speed and elevation of the treadmill according to a pre-set protocol.

Automatic ECG Print-out

The automatic ECG print-out automatically runs an ECG strip at pre-set intervals during the test and recovery period.

All equipment in the laboratory should meet hospital, provincial and federal safety standards.

AMBULATORY ELECTROCARDIOGRAPHY MONITORING SERVICES

PREAMBLE

Ambulatory ECG monitoring is non-invasive diagnostic technique in which a patient's electrocardiogram is recorded continuously over a prolonged period of time (six to 26 hours) while the patient goes about his or her usual daily activities. Popular synonyms include Holter monitoring, 24-hour ambulatory monitoring, dynamic monitoring and continuous ambulatory ECG monitoring. The service consists of two activities, the recording of data and the analysis of data.

There are a number of different methods of recording and analyzing ECG data obtained on ambulatory patients. Some variations include:

1. The patient carries a portable tape recorder and activates the recorder only during symptoms. The ECG is stored on tape in the recorder and can be scanned and interpreted at a later date by the physician. In this situation, the patient's electrocardiogram is available only when he activates the recorder during symptoms.

2. The patient carries a portable magnetic tape recorder which is activated continuously (6-26 hours). At the end of this period, the tape is scanned and the physician has available the patient's ECG pattern for the whole length of time, whether the patient has symptoms or not.

   The above two methods are those most widely used and are the ones referred to in these guidelines.

3. Other methods such as trans-telephone and radio transmission of the ECG are also available.

Ambulatory ECG monitoring is most useful for the detection, identification and quantification of cardiac arrhythmias, conduction disturbances and ST segment shifts. It is also useful in relating the patient's symptoms and specific activities to the simultaneously recorded ECG, as well as in helping to define the prognosis of patients following a myocardial infarction, and in the follow-up of patients with pacemakers.

Indications and Objectives of Ambulatory ECG Monitoring

There are two general indications for this type of monitoring, as well as numerous situations in which ambulatory ECG monitoring may be useful in particular clinical disorders. The two general indications are:

1. Determination of the ECG correlates of symptoms suspected to be of cardiac origin.

2. Evaluation, treatment and rehabilitation of patients with coronary artery disease.

Evaluation of specific rehabilitative activities is another indication for ambulatory ECG monitoring of patients with coronary artery disease. It provides the physician with information on the patient's heart rate's response to daily activities, as well as the presence or absence of cardiac dysrhythmias or ST segment changes.

The decision to develop ambulatory ECG monitoring in a community will depend to a large extent on a balance between the rather high cost of the equipment, together with the availability of specialized personnel to perform the technique, and the number of patients who are expected to benefit from the technique.

These guidelines refer to two levels of service as follows:

(a) a recording service - which consists of recording activities only (where the patient-load does not justify the cost of scanning equipment),

(b) a complete service - which consists of both recording and scanning services. Training and research are provided only at the level of the complete-service facility.

GUIDELINES

1. PATIENT-LOAD

To be most useful, ambulatory ECG monitoring should be available to patients in their usual environments. The recording devices should be as widely available as possible at the community level. The quality of the recording is highly dependent on competence in application of the electrodes and local personnel should be trained in this regard.

In smaller communities, one recorder per 50 patients per year should be available. Where the caseload does not reach 50 per year, lending or leasing arrangements with the institution providing the scanning service should be made.

A minimum volume of 500 cases per year is necessary to support rapid playback and scanning equipment. If the volume reaches 2000 cases per year a second scanner will be needed.

2. BED REQUIREMENTS

No active treatment hospital beds are required to support this service.

3. RECOMMENDED DISTRIBUTION OF UNITS

Two levels of facilities should be developed as stated in section 1. These should be organized, taking into consideration factors such as variation in patient population, geographic isolation and the availability of this service in nearby hospitals.

Major Teaching Hospitals or Large General Hospitals

Such centres should have facilities available both for the recording and the scanning and interpretation of the ambulatory ECG recordings. Such facilities should be capable of handling tapes which have been

recorded and sent in from outlying hospitals, and of providing rapid reporting (24 hours) in the case of life-threatening arrhythmias.

Smaller General Hospitals or Communities

In this setting only the necessary recording equipment is required. The recorded tapes would be sent to a centre with scanning equipment for analysis and interpretation of the results.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Medical Direction

A hospital providing an ambulatory ECG monitoring service should designate a physician to direct these services, whether the facility consists only of a recording capability or a complete recording and scanning facility. In the smaller community where only recording facilities are available, the service should be directed by a physician with a special interest in ambulatory monitoring. In the larger facility where both recording and scanning equipment are available, the director should be a qualified cardiologist or qualified internist with special interest in this field. For purposes of standardization and quality control, it is essential that there is frequent communication between the two levels of ambulatory ECG monitoring facilities. The director of the central scanning facility, with input from designated physicians in the outlying communities, should be responsible for overall policy concerning techniques, procedures, quality control and interpretation.

4.2 Policies and Procedures

Policies and procedures should be clearly defined in writing and should be uniform for all laboratories using a particular central facility. They should include statements concerning:

- the responsibilities of the director of the laboratory;

- the responsibilities of the physicians interpreting ambulatory monitor recordings;

- the responsibilities of technical staff involved in ambulatory monitoring at both levels -- that is, at the community level and at the central scanning facility;

- the final responsibility for sending the official interpretation of the test to the referring physician and to record the interpretation on the patient's hospital chart;

- the frequency of routine safety inspections of laboratory equipment and the procedures to be performed during the inspections;

- the indications for the procedure;

- the implementation of a quality control program to evaluate the accuracy of scanning and interpretation.

4.3 Responsibilities of Staff

Responsibilities of the staff should be clearly defined in writing. It is the responsibility of the:

- clinical director of the complete service facility to co-ordinate the overall activity of the central scanning laboratory as well as co-ordinate the overall function of the regional referral system;

- designated physician to supervise the overall activity of the service at the local recording service level;

- technical staff (technologists), to ensure that the equipment is in working order, to prepare the patient for the ambulatory monitor recording and to analyze[3] data on the scanning equipment and generally attending to the patient's needs.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Medical Staff

- A director of a complete service facility should be designated by, and responsible to, the hospital and the appropriate clinical director of service, usually cardiology.

- Where a hospital has an ECG laboratory, the director of that laboratory should be designated director of the ambulatory ECG monitoring service.

- Where a hospital ECG laboratory is not available, a designated physician may be responsible for local arrangements.

5.2 Technical Staff

The technical component of obtaining ambulatory ECG recordings requires different levels of competence and skill depending on whether the technologist is working in a smaller community facility, which uses ambulatory ECG recorders only, or whether the technologist is also responsible for analyzing tapes with scanning equipment.

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3 The term analysis, used throughout the guidelines, refers to preliminary analysis carried out by the technologist, but does not include final interpretation of the test results, which is the responsibility of the physician.

Limited Service Facility

An ECG technician attached to the hospital's ECG department can be responsible for preparing a patient for ambulatory ECG monitoring, caring for the recorder and sending the completed tapes to the central scanning facility.

Complete Service Facility

The technologist in this facility would be responsible both for preparing the patient for an ambulatory ECG recording and for analysis of the monitor tapes. In such a setting, the technologist may be a member of a larger cardiac non-invasive or special cardiac procedures laboratory and may share the responsibilities in ambulatory ECG monitoring with other trained technologists in the laboratory, as well as performing other non-invasive tests.

It is important that the technologist performs enough ambulatory ECG monitoring procedures per year to maintain a high level of competence. It is suggested that 100 cases per year be a minimum number of analyses per technologist.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Clinical Director: For the complete-service laboratory, the director should be a qualified cardiologist or internist with a special interest in ambulatory ECG monitoring. For the community facility with recording capabilities only, the designated physician could be a qualified cardiologist or internist, or another medical practitioner with an interest in ambulatory ECG monitoring. All interpretations should be performed by a qualified cardiologist or internist.

Technical Staff

Basic training as an ECG technician is necessary for technologists at both levels of service. For technologists working at the recording service level, a few extra hours of special training at the central facility, under supervision, in the technical aspects of the ambulatory ECG recorder and in preparing the patient for the recorder should suffice. For the technologist in the central scanning facility, special training in the use of equipment, as well as in the detection and recognition of arrhythmias, is essential. Certification by provincial or national associations is recommended.

6.2 Continuing Education

This includes post-graduate courses, conferences, seminars, in-hospital courses, programmed instruction and visits to special centres.

Supervising Medical Staff

A minimum of one post-graduate course of conference per year for all supervising staff is desirable. Part of that post-graduate course or conference should involve ambulatory ECG monitoring.

Technical Staff

The technologist in the small community hospital should have his or her technical skills and methods updated every year. A visit to the central scanning laboratory each year for this purpose is recommended.

Technologists associated with larger central scanning facilities, which may often be part of larger non-invasive laboratories, should attend a course, conference or seminar, etc., related to ambulatory ECG monitoring a minimum of once every three years. Such technologists should participate in ongoing educational activities related to non-invasive techniques in general. Larger facilities will often

have a number of technologists and physicians involved in non-invasive procedures and the continual interchange of information and knowledge in these laboratories should serve to maintain a high level of competence and knowledge in the techniques.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

7.1 Biomedial Engineering: This service is necessary for routine repairs and maintenance of equipment, as well as routine monthly safety checks on electromedical equipment. Availability of this service from an off-site source will suffice.

7.2 Efficient communication, mailing and transportation systems are essential.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Recording Service Facility

It is recommended that the ambulatory ECG monitoring facilities be part of the hospital ECG service. In this situation, no extra space is required since the patient may be prepared for the procedure using the same facilities that are used to obtain out-patient electrocardiograms.

8.2 Complete Service Facility

Whether the central scanning facility is part of a large non-invasive laboratory or not, a single quiet room of $9.3m^2$ is necessary to house the scanning equipment and to facilitate the analysis of ambulatory ECG recordings. Space will also be necessary for interpretation and for storage of records.

As with other out-patient facilities, there must be a patient's waiting and reception area. If the facility is part of a larger non-invasive laboratory,

there is no particular advantage for the ambulatory ECG monitoring facility to be in proximity to the ECG department. Since ambulatory monitoring usually involves a large out-patient population, a location easily accessible to the public is desirable.

9. EQUIPMENT

The basic equipment necessary to perform good quality ambulatory ECG recordings includes:

9.1 Portable Recorders

The frequency response of the recorder must meet American Heart Association's standards. Of the current one- and two-lead systems, the two-lead system is preferable.

9.2 Rapid Playback and Scanning Equipment

Important features of this equipment include easy operation and a frequency response which meets American Heart Association's standards. The equipment must include a capability for direct ECG write-out. Arrhythmia detection computers are not essential, but allow much faster analysis of tapes, and therefore more cost-effective use of technologist's time. The limitations of these computers must be appreciated.

9.3 Miscellaneous Equipment

This would include ECG electrodes, patient cables, ECG voltage calibrators, rechargeable batteries and rechargeable battery chargers, magnetic tape demagnetizer and eraser, as well as extra supplies of tapes, reels or cassettes.

Ambulatory ECG monitoring is an area in which advances in hardware, microprocessors and software will continue to occur. These advances may increase the usefulness, volume and effectiveness of this technique.

ECHOCARDIOGRAPHY UNITS[4]

(INCLUDING CARDIAC DOPPLER TECHNIQUES)

PREAMBLE

Echocardiography is a safe, non-invasive, non-ionizing, easily repeatable diagnostic examination that, in skilled hands, provides reliable and valuable information on the structure and function of the heart. The basis for diagnosis is the evaluation of the size, position, configuration and motion of structures of the heart, the assessment of anatomical relationships within the heart and the assessment of cardiac function.

Echocardiography has certain advantages over many other diagnostic techniques. Most importantly, the method is non-invasive and can be performed repeatedly without known hazard to the patient. Moreover, with this one examination, it is possible to assess with considerable precision the cardiac valves, pericardial-epicardial space, thickness of the myocardium, chamber dimensions in systole and diastole and the presence or absence of space-occupying lesions within the heart, and accurately evaluated global as well as regional left ventricular wall motion. Complex congenital malformations may be reliably diagnosed by the experienced operator. The addition of doppler capabilities allows for more accurate evaluation of valvular abnormalities.

It is important to emphasize that the following guidelines need to be interpreted in the light of rapidly evolving advances in both the technological and delivery aspects of diagnostic echocardiography.

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4 See also: Diagnostic Imaging Services and Systems, an Overview; Guidelines for Special Services in Hospitals, 1982, Health Services Directorate, Department of National Health and Welfare.

For instance, as experience with the relative benefits of doppler techniques accrues, echocardiography without doppler may become the exception.

GUIDELINES

1. PATIENT-LOAD

Echocardiography provides a diagnostic service for both in-patients and out-patients. A minimum anticipated annual work load of at least two or three examinations per working day (500-700 examinations per year) is necessary to justify the development of an echocardiographic service. Currently, between 40 per cent and 50 per cent of these may be expected to involve doppler. This may require consolidation of caseloads within certain communities. Less than the recommended minimum caseload may be acceptable under special circumstances, such as a remote geographic location.

The maximum echocardiographic work-load that one technologist, using one machine, can accommodate is estimated to be between seven and twelve cases without doppler per day, depending on variables encountered in the examinations. However, for those examinations incorporating doppler ultrasound, 30 minutes will be added to each procedure.

In a university-affiliated teaching hospital, additional time may be required to train physicians to perform and interpret echocardiograms.

2. BED REQUIREMENTS

No specific beds are required for this service.

3. RECOMMENDED DISTRIBUTION OF UNITS

Echocardiographic facilities should be available in referral cardiac centres (which incorporate the services of two or more full-time cardiologists) and in university-affiliated teaching hospitals. The

decision to develop additional units should be made on the basis of needs and resources in each geographic area.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Medical Direction

The services provided to patients by an echocardiography unit should be under the clinical supervision of a designated physician, such as a cardiologist, radiologist, internist or pediatrician, who is fully trained in the field of echocardiography.

4.2 Administrative Direction

The designated physician should have the overall responsibility for the administration of the service.

4.3 Policies and Procedures

Policies governing these services should be developed by the physician in charge.

These policies should be approved by the Board of Trustees on the recommendation of the Medical Advisory Committee, and/or the administration as appropriate, and should include the following:

- Indications for echocardiography services and policies regarding who may order them.
- The report of the patient's study to consist of both measurements and a summary interpretation and should be a part of the patient's record.
- Echocardiographic recording reports of all patients studied to be filed in the unit or in an easily accessible location.
- Adequate unit records and statistics to be maintained.

- Information outlining indications for echocardiograhy should be circulated to the attending medical staff.

5. STAFF ESTABLISHMENT AND COVERAGE

The minimal staff requirements for an echocardiography service are a medical director and a technologist. Secretarial services are also necessary.

Since this service should be available on a continuous basis, provision should be made for 24-hour, on-call coverage.

It would be advantageous for a number of technologists working in a non-invasive cardiac laboratory to be trained in all non-invasive techniques in order to maintain services during vacations or sick time.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Medical

The medical director should hold certification from the Royal College of Physicians and Surgeons of Canada, or its equivalent, in a specialty such as cardiology, radiology, pediatrics or internal medicine. Equally important, he/she should be thoroughly conversant with the principles of echocardiography and doppler techniques and should be fully trained in the use of the equipment and the interpretation of both types of tracings. He/she should be able to provide educational programs in the technique of echocardiography.

Technical Staff

Technologists are capable of recording the vast majority of echocardiograms if adequately trained and appropriately supervised by a physician.

Training requirements for echocardiographic technologists are at present undergoing considerable study, both in Canada and the U.S.A. The American Society of Echocardiography suggests that persons who have graduated from courses such as nursing, laboratory technology, radiology technology, respiratory technology or equivalent would require only a 12-week structured program in echocardiography, followed by a comprehensive examination. Another suggested approach for persons with similar backgrounds is a one-year program in medical sonography with echocardiography being only one aspect of the material taught. Obviously, on-the-job training in established laboratories will continue (for some time) to be an acceptable training format for technologists. Technologists in centres adding doppler capabilities will require further training in these techniques. Until an examination is developed in Canada, all echocardiographic technologists should be encouraged to take the examinations of the American Society of Ultrasound Technologists or the American Society of Echocardiography in order to ensure a minimal standard of knowledge.

6.2 Continuing Education

Medical

The medical director should undertake regular training by participation at the ultrasound sessions of the Canadian Cardiovascular Society, the American Institute of Ultrasound in Medicine, the American Heart Association and other similar organizations, to keep abreast of new knowledge and techniques in the area of echocardiography and doppler examinations.

Technologist

Echocardiographic technologists should be given the opportunity of attending sessions, seminars or training courses in other centres to regularly update their knowledge in echosonography.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

Biomedical engineering services should be available.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

The minimum total space required for each ultrasound machine dedicated to cardiac investigation includes the following (based on 500-700 examinations annually):

(a) a laboratory of 18.5m^2 designed so that a stretcher can easily be moved in and out. The laboratory will contain a single bed in addition to the necessary equipment. It is preferable that the echocardiography unit be housed in a closed room with no other functions except phonocardiography, pulse wave analyses and doppler if the latter is available. The space, however, could be shared with general ultrasound services.

(b) a work space to prepare and interpret records - 11.2m^2.

The following should be available, but not necessarily in the facility:

- an office for the medical director 7.4m^2;
- office space for professional and secretarial staff 7.4m^2;
- a darkroom if photographic equipment is being used 5.6m^2;
- a change room, lockers, and toilet facilites for out-patients (may be shared) 9.30m^2.

9. EQUIPMENT

A basic two-dimensional echocardiography machine complete with strip chart recorder and video cassette recorder is the most acceptable equipment and will provide the proper level of information. If doppler equipment is contemplated, it should include both continuous wave and pulsed wave capability, and should give a spectral analysis of blood flow.

There are stringent electrical safety requirements for this type of equipment. Echocardiography is sometimes used in the cardiac catheterization laboratory or in intensive care units in which direct access to electrical energy to the heart is possible.[5]

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

The echocardiography unit should be an integral part of a cardiac investigation unit and should work in close association with other available sections of that unit, including phonocardiography, electrocardiography, stress testing, cardiovascular nuclear medicine and cardiac catheterization. This is particularly important to ensure appropriate patient investigation and to facilitate physician's education on an on-going basis.

When choosing a location for the unit, it is important to recognize the potential value of the unit to critical care areas such as the Cardiac Care Unit and Intensive Care Unit. The equipment, although "portable", is delicate and can be damaged by movement over rough areas, especially entering and leaving elevators. The unit should be readily accessible to ambulatory patients.

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5 "Report of the Inter-Society Commission for Heart Disease Resources - Optimal Resources for Ultra-Sonic Examination of the Heart", Circulation June, 1975, p. 4.

CARDIOVASCULAR NUCLEAR MEDICINE

It is essential that these guidelines be considered in conjunction with the nuclear medicine guidelines.[6]

PREAMBLE

Cardiovascular nuclear medicine is defined as the use of radionuclides in diagnosis and investigation of the heart and circulatory system. Recent technical developments in nuclear instrumentation and radio-indicators have increased the importance of radio-nuclide studies in diagnostic cardiology. Interest in this field has increased, both because of the relatively non-invasive nature of the diagnostic procedures and because the physiological data provided are often unique.

Because of the complexity, the common features of much nuclear diagnostic equipment and the medical and technical expertise required for its proper use, hospitals developing nuclear medicine services should begin by developing a central nuclear medicine facility capable of providing a broad range of diagnostic studies, including cardiovascular studies. (See nuclear medicine guidelines). As case loads and staff capabilities expand, it may be desirable to establish physically separate units either in proximity to specialized cardiac diagnostic and therapeutic services, or to special care areas. When the work load does not justify such separate units, mobile diagnostic equipment, originating from the central nuclear medicine facility, may be used. Satellite units should be functionally and administratively related to the central facility in order to facilitate consultation and to provide for equipment back-up

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6 Nuclear Medicine Units in Hospitals; Guidelines for Special Services in Hospitals, 1985, Health Services Directorate, Department of National Health and Welfare.
Diagnostic Imaging Services and Systems, an Overview, idem. 1982.

and more sophisticated data processing and professionally closely related to the cardiology units and the non-invasive vascular laboratory. Mobile equipment is a necessary part of a nuclear medicine unit; in addition to providing services to satellite units, it is also required in a facility with a unit in order to carry out diagnostic imaging on patients who are unable to be moved, e.g., cardiac-surgery patients.

Diagnostic Applications

The types of cardiovascular radionuclide procedures to be made available depend on both the range of conditions of the patient population served and the range of other therapeutic and diagnostic services provided (e.g. cardiac catheterization, coronary angiography, coronary bypass surgery and acute cardiac care).

The major diagnostic applications are: radionuclide ventriculography, which would include cardiac output, ventricular wall motion, visualization and measurement of ejection fraction, myocardial perfusion imaging, acute myocardial infarction visualization, pulmonary ventilation and perfusion scanning, effects of drugs and exercise and detection of peripheral venous thrombiosis.

The field of cardiovascular nuclear medicine, including the indications for its use, is a rapidly developing and changing one. Facilities must be designed to have sufficient flexibility to meet these changing needs. Continual evaluation of new techniques is required, using the criteria of clinical usefulness, suitability to the needs of the patient population served and institutional priorities.

GUIDELINES

1. PATIENT-LOAD

In most hospitals, cardiovascular nuclear medicine will be one function of the nuclear medicine department.

Establishment of a sub-unit of the nuclear medicine department, dedicated to cardiovascular nuclear medicine, may be justified either on the basis of clinical demand or physical location. Assessments of three to five patients per working day or 1000 patients per year are necessary for such a sub-unit to be economically viable in terms of equipment cost and technician time. Beyond 1000 studies, depending on their nature, consideration may need to be given to a second camera.

If the intensive care and cardiac care units are located near the nuclear medicine department a separate sub-unit may be unnecessary. In institutions with an insufficient workload to justify a separate sub-service.

These studies are being done on both in-patients and out-patients.

2. BED REQUIREMENTS

There are no specific bed requirements for the service.

3. RECOMMENDED DISTRIBUTION OF UNITS

As stated in the guidelines for nuclear medicine, for a two-tiered system of delivery for services is suggested. At present, it is not realistic to establish nuclear medicine units in hospitals with fewer than 200-250 active treatment beds, although in certain instances regional services extending to an equivalent population base may be justified, particularly for out-patient studies.

In hospitals with more than 200-250 beds, with Type II nuclear medicine units, selected cardiovascular nuclear medicine procedures should be available. These procedures may include radionuclide angiography, acute myocardial infarction imaging, regional myocardial perfusion measurements, regional pulmonary perfusion and labelled fibrinogen studies. The qualifications of the medical staff and the availability of other support facilities must be considered in establishing the capabilities of a cardiovascular nuclear medicine unit.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Medical Direction

In this text the term "cardiovascular nuclear medicine physician" will refer to a nuclear medicine specialist with special training in cardiology or to a cardiologist with special training in nuclear medicine.

A cardiovascular nuclear medicine physician should be appointed as medical director of the cardiovascular nuclear medicine sub-unit. Because of the wide range of knowledge required in both nuclear medicine's techniques and cardiovascular physiology, performance and interpretation of diagnostic modalities should be a joint responsibility of the cardiovascular nuclear medicine physician and the patient's cardiologist/internist.

The division of responsibilities between the cardiovascular nuclear medicine physician and the referring cardiologist/internist should be a flexible one, capable of accommodating the specialist skills and variable interests of both. The cardiovascular nuclear medicine physician responsible for the technical aspects of the examination may also be responsible for varying degrees of clinical involvement.

The technical aspects of examination must be the responsibility of the cardiovascular nuclear medicine physician. Cooperation between that physician and the referring cardiologist/internist is required for selection of procedures to be performed and planning for examinations for individual patients.

In some hospitals the cardiovascular nuclear medicine sub-unit could be organized and supported on a separate financial basis in order to ensure the necessary development of this high priority service. In university affiliated hospitals, the sub-unit should have sufficient reserve capabilities to meet the requirements of research and development as well as service.

See also Section 3.1 "Medical Direction" in the guidelines Nuclear Medicine in Hospitals.

4.2 Policies and Procedures

Refer to Nuclear Medicine in Hospitals.

5. STAFF ESTABLISHMENT AND COVERAGE

Because nuclear medicine procedures require knowledge of advanced nuclear and computer technology, physiology, pathophysiology and clinical judgment, personnel with diverse expertise are needed.

5.1 Medical Staff

Cardiovascular nuclear medicine physicians evaluate patients before every diagnostic study, interpret examination results and consult with referring physicians. Depending upon the level of nuclear medicine facilities, the services of a cardiovascular nuclear medicine physician should be available on a full- or part-time basis. Responsibilities of a cardiovascular nuclear medicine physician include radiation safety, quality control of instrumentation, teaching of medical physics and nuclear instrumentation and application of new technology. Skill in computer use is essential.

Nuclear medicine equipment maintenance, whether performed in-house or under service contract, should be under the jurisdiction of the cardiovascular nuclear medicine physician.

5.2 Radiation Scientist

The services of a nuclear medical physicist should be available on a consultative basis. His or her responsibilities should include radiation safety, quality control of instrumentation, the teaching of medical radiation physics and nuclear instrumentation to the medical and technical trainees and staff, and the evaluation of new instrumental techniques. Skills in computer programming are particularly desirable. Alternately, the function of the physicist can be filled by an engineer with special training in nuclear instrumentation.

5.3 Technical Staff

Registered technologists (nuclear medicine) should be employed whenever possible. Their ability to perform both in vivo and vitro procedures permits rotation of staff for greater experience and interest and allows for coverage of the service during sickness and vacation leave. In some instances it may be useful to have a dedicated technologist remain in the unit as a coordinator and to develop special skills. A technologist should be capable of performing other associated tests, such as both the electrocardiogram and the myocardial scan during an exercise study. In most instances a trained exercise technologist should be available during stress testing.

As stated in the nuclear medicine guidelines, the other personnel required depends upon the level of the unit, i.e. Type I or Type II. In the latter, an experienced technologist prepares the radiopharmaceutical agents. In the major medical centres, this task is generally performed by a radiopharmaceutical chemist or radiopharmacist. This is particularly essential when special radio-indicators need to be prepared.

5.4 Other

For role definitions of radiation scientists, registered nurses, clerical staff and ancillary staff please refer to the guidelines on Nuclear Medicine in Hospitals.

5.5 Emergency Response Capability

Where exercise testing is performed a physician trained in Advanced Cardiac Life Support must be immediately available. All staff in the unit should be trained in Basic Cardiac Life Support.

6. STAFF TRAINING AND QUALIFICATIONS

As noted in 4.1, the performance of cardiovascular nuclear studies should be the responsibility of the nuclear medicine physician.

For guidelines on staff training and qualifications please refer to the guidelines, Nuclear Medicine in Hospitals.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

In some institutions liaison with pharmacy and biomedical engineering is advantageous, while the radiology film developers may also be used.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

Please refer to the guidelines Nuclear Medicine in Hospitals.

For a separate, single camera sub-unit performing 1000 examinations annually, a minimum ara of $28m^2$ would be required for the purposes of in-patient/ out-patient studies. This area would contain a single bed, the imaging equipment, storage space and desk space. An additional $10m^2$, is necessary to accomodate the related computer facilities, videotape

equipment, viewing and reporting. The entire suite should be provided with airconditioning and line voltage regulation and surge suppression.

Arrangement should be such that the technologist can move freely around the table during the examination procedure. Both oxygen and suction should be available, with emergency resuscitation equipment ("crash cart") located nearby. Unless the hospitals' cardiac stress testing laboratory is located immediately adjacent to this laboratory, an additional room with cardiac-stress-testing equipment may be necessary. If stress testing is being performed in the unit a defibrillator must be also kept within the unit.

9. EQUIPMENT

The most generally useful piece of equipment for cardiovascular nuclear medicine studies is the scientillation camera incorporating a digital computer with up-to-date software.

The technical specifications of the equipment should meet the requirements for the spatial and temporal resolution necessary for cardiovascular work, especially in regional myocardial blood flow and radionuclide angiography.

The digital computer is essential for many cardiovascular studies. It enables ECG cardiac blood pool studies, facilitates the obtaining of certain quantitative measurements such as stroke volume and ventricular ejection fraction and improves image quality, thereby improving demonstration of regional abnormalities in wall motion. A "hard wire" special purpose system or general purpose programmable computer can be used.

Non-imaging detectors, sometimes called probes, may be used in research facilities to measure cardiac output, ejection fraction, left to right shunting and transpulmonary transit time.

Unless the stress testing laboratory is immediately adjacent, an exercise ECG machine, a treadmill and resuscitation equipment are also necessary. If exercise radionuclide ventriculography is to be performed, a specially designed exercise table is mandatory.

The performance of nuclear medicine procedures in the cardiac care unit, intensive care unit, cardiac operating room, catheterization laboratory or emergency room requires the immediate availability of specialized equipment (e.g. mobile scintillation camera) and committed storage space for instruments and radiopharmaceutical agents.

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

Close geographic relationships are desirable between cardiac nuclear medicine and nuclear medicine, other cardiac services, the intensive care unit and other non-invasive cardiac services.

The location of the facilities should be determined by consultation between hospital administration and the physicians involved.

PHONOCARDIOGRAPHY

Phonocardiography is a non-invasive technique that graphically registers the mechanical vibrations produced by cardiac activity (i.e. heart sounds and murmurs). It is most commonly used as an adjunct to auscultation but should always be combined with external pulse recordings and an electrocardiogram for correct interpretation. Such multi-channel recordings also allow extension of the technique to the non-invasive assessment of left ventricular performance by systolic time interval measurements. Phonocardiography is used primarily to clarify findings made on auscultation and is of particular value in establishing the exact timing of extra heart sounds or murmurs. It is a technique of major teaching value.

Phonocardiography services should be available to all university affiliated teaching hospitals which have a medical residency teaching program. The development of this facility in other hospitals will depend upon: (1) the availability of a certified cardiologist or suitably trained internist with interest in and knowledge of these techniques; (2) the time commitment of a qualified individual, sufficient to provide services and to maintain competence, and (3) an adequate number of procedures, averaging several cases per week, to maintain the competence of those performing phonocardiography.

SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

The phonocardiography equipment should be located in an enclosed room which has adequate sound insulation. To prevent difficulties with artifacts in the recordings, there should be no extraneous noise from forced air heat, air conditioners, water pipes and running water. In institutions where phonocardiography and echocardiography are available, these procedures are usually performed in the same room.

EQUIPMENT

A wide variety of phonocardiography equipment is available. The equipment should have a minimum of four channels. This allows simultaneous recording of the electrocardiogram, carotid pulse tracing, phonocardiogram and apexcardiogram, or alternatively a second phonocardiography channel for simultaneously recording from a second area on the chest surface.

RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

The phonocardiography units should be an integral part of the cardiac investigation unit and work in close association with other available sections of that unit, including the echocardiography services, ECG service and cardiac catheter facility.

NON-INVASIVE VASCULAR LABORATORIES

PREAMBLE

The traditional approach to the assessment of a vascular problem using history and physical examination has limitations. The introduction of angiography has improved the accuracy of assessment, but the procedure has certain risks and may require hospital admission.

In recent years, improved instrumentation and techniques have resulted in reliable methods for the non-invasive detection, localization, and quantification of diseases affecting peripheral arteries and veins. As a result, hospital-based vascular laboratories have evolved and have been found to be useful for patient evaluation. The report of the Intersociety Commission for Heart Disease Resources sponsored by the U.S. Department of Health, Education and Welfare pointed out that proper application of non-invasive techniques in a well-supervised vascular laboratory or, in a simplified form, in the physician's office will result in a more precise definition of vascular symptoms, better identification of patients who may benefit from surgical or medical therapy, and ultimately lead to a reduction in health care costs.[7]

The guidelines which follow are intended to be of help in planning and developing facilities for non-invasive investigation of vascular disease. It is important to emphasize that the following guidelines must be interpreted in the light of rapidly evolving technological advances in these diagnostic procedures. The requirements of a specific facility will depend upon the scope of its activity and its relationship to other laboratories and facilities of the institution and the community.

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7 Circulation, Volume 54, A-1, 1976.

DIAGNOSTIC APPLICATIONS

Non-invasive techniques are useful in the assessment of patients with variety of peripheral vascular disorders. The list which appears in Supplement I (page 67) indicates the potential scope of activities of vascular laboratories. Which of these techniques may be included in the activities of any specific laboratory will depend on its size, resources, and on the internal organization and the activities of the institution and the area served by the laboratory.

Supplement II (page 69) outlines briefly some of the commonly used diagnostic methods. Detailed description of the methods and applications is beyond the scope of these guidelines. Interested parties are referred to the publication entitled Non-invasive Diagnostic Techniques in Vascular Disease, Volume III published by C.V. Mosby Company, 1985.

GUIDELINES

1. PATIENT-LOAD

It is desirable that at least 600 studies be done per year in a vascular laboratory. A study constitutes a patient evaluation for either peripheral arterial or venous disease, or for cerebrovascular disease. This volume is usually generated in a major hospital with active surgical services which perform vascular reconstructive procedures on a continuing basis.

2. BED REQUIREMENTS

Not applicable.

3. RECOMMENDED DISTRIBUTION OF UNITS

As indicated above, this service is usually located in a general hospital providing vascular surgery.

Since out-patients may form a large proportion of the patients referred for assessment to a vascular laboratory, such a laboratory may be attached to a large clinic, a cardiovascular rehabilitation facility, or a small hospital whose laboratory may be shared with other institutions.

Under certain circumstances, where the volume of cases indicates, it may be feasible for several hospitals to share a vascular laboratory.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

A physician should be appointed as director of the vascular laboratory and should have overall administrative responsibility. The director should ensure that the procedures are carried out accurately and that reports are processed rapidly. Policies must be established by the director to include: patient selection; methods of referral and reporting;

environmental safety; emergency procedures; quality control and review of the results; teaching and research.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Medical Staff

The director of the unit should be a physician with expertise in the diagnosis of vascular disease, and with detailed knowledge of non-invasive testing instrumentation and techniques. In the case of larger facilities with heavier workloads, it is desirable that one or more additional physicians with expertise in vascular disease be available to support the director and participate in the activities of the laboratory. The activities of the laboratory should be developed and co-ordinated to meet the needs of both the medical and surgical services of the hospital.

5.2 Nursing and/or Technical Staff

A nurse or a technician can be trained to do most of the procedures but a physician should be readily available to intervene if necessary. Since a significant amount of patient contact and assessment is necessary, a full-time registered nurse is preferable. If technicians are employed the minimum prerequisite should be radiology or ultrasonography training, so that they have the required knowledge of anatomy, physiology and pathology of vascular disease. In larger laboratories a nurse and one or more nurses/technicians may be needed.

5.3 Secretarial Staff

Depending on the size of the facility, a part-time or a full-time secretary is needed.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Medical

The director of the vascular laboratory should be chosen from physicians with special interests and qualifications in the diagnosis of vascular diseases. Training of physicians in the interpretation of non-invasive tests depends on their background but, in general, three to six months' training in a vascular laboratory, and the assessment of 250 or more patients under supervision, are adequate.

6.2 Nurse and/or Technician

A nurse and/or technician may obtain adequate training in about eight weeks in a vascular laboratory. With the anticipated further development of societies interested in continuing education for vascular laboratory technologists, it is expected that formal training programs and licensing examinations will be established. Attendance at prescribed courses would be desirable. Such training is essential since the nurse/technician must correlate the history and physical findings with the results of the studies in order to obtain adequate reproducible results.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

There should be close liaison between the vascular laboratory and vascular surgery, cardiovascular surgery, general internal medicine, cardiology, radiology (angiography) and nuclear medicine. Depending on the individual institutional organization, the activities of the laboratory may require close liaison with a neurosciences program (cerebrovascular disease). In addition, a close liaison with biomedical engineering services is desirable.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

A vascular laboratory would usually be based in a hospital and would serve both in-patients and out-patients. For the minimum number of studies (600) an area of approximately $37.2m^2$ is needed for the laboratory. An added $20.9m^2$ is needed for each additional 400 patients studied. It would comprise the patient examination area(s) with bed(s) and equipment, a reporting area, and secretarial space including filing space. Access to a waiting area is necessary. Strict adherence to electrical safety regulations is essential (see also the section on electrical requirements in guidelines for the intensive care unit).

9. EQUIPMENT

The basic equipment required for a non-invasive vascular laboratory need not be unduly expensive. Inexpensive commercially available doppler ultrasonic flow detectors, which are useful for a variety of applications, would be commonly included, but various other equipment may be utilized depending on the scope of the activities of the laboratory (See Supplement I, page 67).

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

Since both in-patients and out-patients will be served by the vascular laboratory, a geographic location which is easily accessible to outpatients is desirable.

SUPPLEMENT I

POTENTIAL SCOPE OF ACTIVITIES OF VASCULAR LABORATORIES

1. **Arterial Disease of the Lower Extremities** (Intermittent claudication, rest pain, skin ulcerations and gangrene).

   - Resting pressure measurements using blood pressure cuffs at the levels of the toes, ankles, calves, lower and upper thighs.

   - Assessment of the response of ankle pressures to exercise.

   - Arterial waveform recording, with or without quantitative analysis.

   - Arterial imaging.

   - Assessment of sympathetic nerve function (skin temperatures, sweat tests, etc.).

2. **Vascular Disease to the Upper Extremities** (thoracic outlet syndromes, trauma, Raynaud's disease and phenomena, thromboangiitis obliterans, etc.).

   - Segmental pressure measurements at the level of the fingers and in the proximal parts of the extremity.

   - Assessment of cold sensitivity.

   - Digital arterial waveform recording.

   - Assessment of sympathetic nerve function (skin temperatures, sweat tests, etc.).

3. **Assessment of the Vascular Basis of Impotence** (by measures of the penile systolic pressure waveform recordings, nocturnal tumescence).

4. **Cerebrovascular Disease**

- Doppler imaging.
- Doppler spectral waveform analysis.
- Ultrasound B Scan.
- Duplex scan.
- Oculoplethysmography.
- Carotid phonoarteriography.

5. **Peripheral Venous Disease**

- Doppler assessment of obstruction and incompetence.
- Assessment of obstruction of plethysmography.
- Assessment of obstruction of phleborheography.

SUPPLEMENT II

NON-INVASIVE DIAGNOSTIC TECHNIQUES

1. Doppler - Ultrasound

The basic doppler ultrasound equipment is relatively inexpensive and useful in the assessment of various forms of vascular disease.

Continuous-wave doppler ultrasound is emitted from a transducer, penetrates tissue and is reflected back to the transducer by all structures in its path. Moving structures, such as the red blood cells, change the frequency of the returning signal and the reflected sound is shifted in frequency by an amount which is proportional to the velocity of blood flow. The difference between the transmitted frequency and the received frequency is processed electronically to provide (1) an audible signal which may be used by the observer to determine the presence or absence of blood flow and to qualitatively assess it and (2) a recording of the blood flow velocity waveform. The cheaper doppler instruments operate at a five to ten MHz frequency. The cheaper non-directional models are quite useful for simpler applications such as measurements of systolic pressures in limbs with arterial occlusive disease. Somewhat more expensive directional models can resolve the direction of blood flow (forward and/or reverse) and provide additional useful information. The doppler's shift-signals may be processed to obtain a waveform by one of two methods: (1) analogue circuits which produce a waveform proportional to the instantaneous maximum or mean velocities or (2) a frequency analyzer to display all of the doppler shift frequencies. The latter method is preferable and permits the accurate display of the flow velocity waveform.

2. Methods of Examination of the Peripheral Arteries

2.1 Measurement of Systolic Blood Pressures

As a blood pressure cuff is deflated a, doppler flow detector or another sensor such as a plethysmograph may be used to determine systolic blood pressure, i.e., the pressure at which the blood flow starts. Systolic blood pressures can be measured in all segments of the extremites including the digits, but attention must be paid to the appropriate width of the cuff for the segment of the extremity where the pressure is measured since the width of the cuff may affect the values which will be obtained. Measurements in the lower extremities are compared to brachial artery pressure to provide an index of the severity of the disease. The simplicity of this technique and its accuracy and reproductibility make it useful for determining the presence or absence of vascular disease and quantifying its severity for future follow-up. In addition, some laboratories have found that these simple measurements are useful in: (a) helping to establish the level of amputation; (b) predicting the chances of success of sympathectomy or arterial reconstructive surgery; (c) predicting chances of healing of skin lesions in limbs with arterial disease; (d) assessing the status of collateral circulation.

Systolic pressures can also be measured in the fingers and at various levels in the upper limbs to determine the presence of arterial obstructon, whereas measurements of penile systolic pressure are helpful in the assessment of the vascular causes of impotence.

2.2 The Use of Exercise to Assess Peripheral Arterial Disease

Having the patient exercise permits objective assessment of the history, including evaluation of the progression and the relative disability which may result from the combination of cardiac, respiratory

and peripheral vascular disease. Also, ankle systolic blood pressure can be measured immediately following exercise. If the patient has intermittent claudication which forces him to stop walking, ankle pressures almost always fall. This procedure is particularly useful in distinguishing vascular symptoms from those which may be caused by orthopedic or neurologic problems, and in assessment of patients with mild stenotic lesions in whom resting pressure at times may be within normal limits.

Treadmills are the most useful since they allow adjustment of the speed and incline of a walking exercise and standardization of the test. However, they are relatively expensive. When a treadmill is not available simpler forms of exercise (walking in the corridor, toe stands, step tests, ergometers, or flexion extension movements at the ankle) may be utilized.

To assess walking ability on a treadmill with post-exercise pressure measurements, the speed and incline can be adjusted according to the patient's condition. Commonly used speeds vary from 1.5 to 3.0 mph and the incline from 7 to 12 per cent. Combinations such as 1.5 mph and 10 per cent and 2 mph at 7 to 12 per cent have been used by various investigators. Exercise testing should be used with caution in patients with evidence of significant coronary artery disease.

2.3 Velocity or Pulse Waveform Recordings

These recordings are useful for localizing the site of the vascular occlusive disease. Visual inspection of the waveforms may be adequate in certain cases; however, quantitative measurements are preferable. Waveforms can be conveniently recorded using doppler equipment, but other methods such as mercury-in-silastic impedance or other types of plethysmography also can be used. The waveform recordings are particularly useful in: (a) some patients with occlusive disease in whom systolic pressure cannot be reliably determined because of

the rigidity of the arterial wall secondary to medical calcification; (b) recordings from over the femoral arteries to assess more proximal arterial obstruction.

2.4 Ultrasound Imaging

B scan imaging with or without doppler recordings, may be of value in detecting arterial disease localized to sites which can be scanned.

3. Examination of Peripheral Veins

3.1 Venous doppler flow examination

This procedure is useful in detecting thrombi in the major veins such as the iliac, femoral and popliteal; and in detecting and localizing incompetent superficial and perforating veins.

3.2 Plethysmography and Phleborheography

Plethysmography, especially using the impedance recording, and phleborheography have been applied to assess venous obstruction. A number of recent reports suggest that these methods can provide useful, reproducible, quantitative information about venous obstruction.

4. Assessment of Cerebrovascular Disease

4.1 Doppler examination

The use of directional flow detectors is useful in the assessment of extracranial occlusive disease. Doppler auscultation over supraorbital arteries using directional doppler and the responses to the compression of the branches of the external carotid vessels may be useful as a screening procedure for the presence of hemodynamically significant lesions in the internal carotid system.

Doppler scanning is widely used and is most valuable when combined with detached doppler spectral analyses of the waveforms recorded from the common

and internal carotid arteries. For example, measurements of peak frequency and assessment of the severity of flow disturbances are of diagnostic accuracy.

4.2 B scan (Duplex Scan)

The extracranial carotid arteries can be imaged with B mode ultrasound and, with a duplex system, doppler recordings can be made from selected sites.

4.3 Other equipment

Oculoplethysmography and carotid phonoarteriography are also available.

B. Invasive Cardiovascular Investigations

CARDIAC CATHETERIZATION LABORATORIES

PREAMBLE

A cardiac catheterization laboratory is a facility designed, staffed and equipped to provide invasive hemodynamic, electrophysiologic, biochemical and angiographic study of the heart. In these guidelines, cardiac catheterization laboratory refers to a complete facility including one or more procedure rooms.

Cardiac catheterization laboratories originated with the resurgence of interest in cardiac physiology following the Second World War. Interest and development has been accelerated in conjunction with the development of surgical techniques to partially or totally correct congenital heart lesions, acquired valvular disease and coronary artery disease. Diagnostic accuracy, as well as the medical and surgical management of cardiac patients, has improved with the appropriate use of these services.

The following guidelines should provide a basis for the review of existing facilities and the planning of new facilities. The development of cardiac catheterization laboratory services in hospitals should be related to community need, range of specialty programs and the availability of specialized services such as cardiac surgery. Because some complications associated with cardiac catheterization may require urgent surgical intervention, and many of the patients being studied may require surgery on a semi-urgent basis, the availability of a cardiac surgical facility is a prerequisite for the establishment of a cardiac catheterization laboratory.

If a cardiac surgical facility is not located in the same institution as the cardiac catheterization laboratory, the justification for the establishment of such a laboratory is at best doubtful. In such unusual circumstances liaison and arrangements

between this laboratory and a nearby surgical center must be very specific to facilitate patient care and information transfer. Such "affiliated" laboratories should exercise particular caution in accepting unstable or acutely ill patients for study, and high-risk patients should be referred to the surgical centre for stabilization and diagnostic procedures. More complex procedures subject to greater complication rates, e.g. transseptal puncture, transthoracic left ventricular puncture, and myocardial biopsy should not be performed in such laboratories.

Optimal arrangements suggest that infants and children not undergo cardiac catheterization in an institution without an established pediatric cardiovascular surgical program.

A considerable amount of teaching and research centres upon the activities of the catheterization laboratory and can only take place within these expensive facilities. It is, therefore, necessary to avoid overcommitment to purely service needs and to allow for space for extra equipment and personnel required for special research-oriented procedures.

As cardiac catheterization and angiography procedures have become routine and increasingly safe, some institutions have developed out-patient catheterization programs. Experience indicates that these procedures may be safely performed on low-risk patients in hospitals with well-established laboratories. A monitored area must be provided for the patient to be observed for several hours following the procedure. Additionally, facilities must be available for the immediate management and hospitalization of the patient with a complication or deterioration in clinical status.

GUIDELINES

1. PATIENT-LOAD

A cardiac catheterization laboratory with a patient load of over 500 patients per annum has the lowest mortality rate. This is especially pertinent to selective coronary angiography. It is recommended that a minimum of 300 patients be studied annually in any adult heart catheterization laboratory, and a minimum of 150 patients be studied annually in a pediatric heart catheterization laboratory. This minimum requirement does not make optimal use of expensive equipment unless the facilities are used for other angiographic procedures. A case load approximating 1000 patients per year for one cardiac catheterization procedure room would make the best use of equipment and personnel. It is apparent that the degree of sophistication of investigation does influence the number of procedures that can be carried out, and should be taken into account in arriving at an optimal patient load for each facility.

2. BED REQUIREMENTS

Techniques of heart catheterization vary from institution to institution. The use of the transfemoral approach no longer necessitates a hospital stay of 24 hours following cardiac catheterization. The use of a transbrachial approach does not usually necessitate the patient remaining in the hospital following the procedure. In order for a catheterization laboratory to effectively operate on a day-to-day basis, in-patient beds must be available when required for short-term patient stay in those cases where patients are referred from geographically distant communities or where complications arise. Patients referred from other hospitals in the region may, after being observed for several hours, be transported back to the referring institution or be discharged. Centres performing emergency heart catheterizations in infants should be located in close proximity to a neonatal intensive care unit.

Short-stay beds could be located in a surgical day care unit, an observation area, or a specialized reference centre.

3. RECOMMENDED DISTRIBUTION OF UNITS

A cardiac catheterization laboratory should only be established in an area where there is a cardiac surgical program, preferably within the same institution, or where there is a close formal working relationship and affiliation with a cardiac surgical program in the same urban area.

It is estimated that a population base of 500 000 would generate 1000 patients per year. It is imperative that when a new unit is contemplated, a complete review of existing facilities should be undertaken. This review would pay particular attention to the examination of current and projected case loads, the availability of resources in the community, the impact of the new facility on existing facilities and cost/benefits. In many situations it may be demonstrated that expansion of existing facilities would be preferable to establishing a new facility. The final decision to develop a new facility should be based on regional needs and resources.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Clinical Direction

The laboratory director should be appointed by the governing body of the hospital and be charged with responsibility for policy development, quality control and fiscal administration.

In many institutions the physician director will be assisted by a committee representing radiology, cardiology, hospital administration and the laboratory technologists and nurses.

4.2 Administrative Direction

The clinical director should also be responsible for overall administrative direction of the catheterization laboratory. In certain circumstances such administrative direction could be delegated to an appropriate person such as a head nurse or a charge technologist.

4.3 Policies and Procedures

Laboratory policies should be developed and regularly reviewed by the director and a committee representing the physicians using the laboratory. Examples of such policy matters might include:

- Recommendation of granting of clinical privileges.
- Periodic review of physicians' performance and recommendation of renewal of privileges.
- Establishment and monitoring of quality controls.
- Development of annual operating and capital budgets.
- Purchase of equipment and assurance of proper maintenance.
- Supervision of scheduling of procedures.
- Scheduling and conducting of regular (usually weekly) conferences attended by all laboratory personnel to review data for quality, resolve interpretive problems, announce and discuss decisions regarding patients studied, etc.
- Policies related to clinicians performing cardiac catheterization. It is essential that the use of the cardiac catheterization laboratory be limited to those physicians especially trained in such procedures. Physicians with cardiac catheterization laboratory privileges should perform a minimum of 150 procedures per year.

Exceptions may be made in the case of certain research procedures. Low volume, specialized procedures should be performed by specifically designated physicians.

- Policies regarding scheduling intra- and inter-hospital referral, management and transfer of patients for investigation.

- An outline of the arrangements for maintaining 24-hour coverage, seven days per week.

- Policies regarding continuing evaluation. These policies should include analysis of case material, analysis of the technical aspects of procedures, including image-quality control, the quality of data, complications and deaths. This evaluation should be reviewed in relationship to other centres.

- Clinical and administrative lines of authority. These policies should define the relationship of nurses in the area to nursing administration in the hospital, as well as the relationship of technologists to the unit and to other technical services in the hospital.

- Policies regarding patients' safety, including equipment maintenance and electrical safety.

- A directive indicating an adequate statement of patient's treatment.

- A statement concerning adequate record keeping.

- Policies relating to liaison and transfer of patients for cardiac surgical care.

- Policies regarding responsibilities for supervision of patients, care and transfer following angiography procedures, and for identification and management of complications.

- Policies relating to the training and continuing education requirements of physicians and laboratory support personnel.

- Responsibilities of staff. Written policies should be clearly defined regarding the roles, functions and relationships of all members of the unit, medical, nursing, technological and other staff.

In addition to a statement on policies, a procedure manual of the unit's services should be developed and maintained. In general this should include indications for cardiac catheterization, appropriate techniques as applied to that laboratory and an outline of the procedures to be followed during complications.

5. STAFF ESTABLISHMENT AND COVERAGE

The smooth functioning of a laboratory requires the availability of skilled professional and technical personnel. In addition to appropriately trained physicians, this includes nursing personnel, special-procedure technologists, radiologic and/or electronic technicians, radiation physicists and other support staff. Individual members of the team may report administratively to various hospital departments and their services may be shared; when participating in a cardiac catheterization and angiographic procedure, they should function as a well-tuned team under the direction of the responsible physician.

5.1 The Clinical Director

The clinical director of the cardiac catheterization laboratory should be chosen from among the appropriately trained physicians. Duties and responsibilities of the clinical director should be clearly outlined as noted in Section 4.1 and 4.2

5.2 Clinicians Performing Cardiac Catheterization (Users)

Physicians granted privileges in the use of the cardiac catheterization laboratory should be cardiologists and/or radiologists who have had the appropriate training in cardiac catheterization laboratory techniques and the appropriate training in cardiology. It is preferable that a small number of clinicians with a high volume of patients have privileges. A minimum of 150 procedures a year is necessary to maintain expertise; however, these physicians should not be expected to perform more than 600 procedures per year.

5.3 Technical Staff

A minimum of three persons providing technical skills should be available for the operation of any unit. These may be technologists or nurse technologists. This allows for the availability of staff on an emergency basis.

The technicians fulfill the roles of cardiopulmonary technician and monitoring and recording technician.

The cardiopulmonary technician manages blood samples, performs blood gas evaluation calculations, and assists with dye dilution curves. Training should include skills in patient observation and preparation, assistance in acute cardiac care, including resuscitation and related therapeutic efforts. This individual should also be qualified to function as the monitoring and recording technician.

The monitoring and recording technician is responsible for the constant monitoring and recording (as necessary) of physiologic data such as the electrocardiogram. Changes are reported immediately to the responsible physician. The monitoring technician must be alert to any change in patient status and should have no other responsibilities during the

procedure. This position can be filled by the cardiopulmonary technician or a radiologic technologist cross-trained for the role.

5.4 Nurse Practitioner

A nurse practitioner with competence in the cardiovascular field may assume some responsibilities of a physician. These include initial patient workup, education and mental preparation of the patient, post-procedural supervision and outline of follow-up care. During angiocardiographic procedures, the nurse practitioner may share in the responsibility for monitoring and patient welfare or other duties as designated by the responsible physician. Responsibilities can also include supervision of the laboratory nursing and technical personnel.

5.5 Registered Nurses

At least two registered nurses should be available as staff in the cardiac laboratory. Their presence is essential because of the use and supervision of sterile techniques, administration of drugs, etc. The number of registered nurses should be adjusted upward, depending upon the availability of resident staff. The ideal situation would be to have nurse technologists, i.e., registered nurses trained in the technical aspects of cardiac catheterization. This would allow for a larger pool of individuals for on-call coverage who are familiar with both the technical and nursing aspects of catheterization procedures.

5.6 Assistant to Clinical Director

An individual from either the nursing or technological staff should be designated to assist the clinical director. This individual would be responsible for the day-to-day operation of the unit in terms of assuring proper patient flow, the ordering of supplies and the maintenance of equipment.

5.7 Radiology Technologists

There should be at least one and preferably more than one full-time radiology technologist assigned to the laboratory for the proper utilization of radiology equipment that is available in the laboratory. Arrangements should be made with the department of radiology for on call coverage of the catheterization laboratory.

5.8 Radiation Physics

A radiation physicist should be a liaison for establishing a radiation safety program.

5.9 Other Staff

The appropriate ancillary staff, such as cleaning staff, clerical staff and nurses aides, should be provided as required.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Clinical Director

The laboratory director may be a cardiologist, cardiovascular radiologist or pediatric cardiologist. If a cardiologist is director, he should be a certified specialist in internal medicine or cardiology and thoroughly trained in the radiology of cardiac imaging and radiation protection. The radiologist-director should be a certified specialist in radiology with special training in cardiac radiology and those aspects of clinical cardiology essential for optimal patient management in the laboratory. A pediatric cardiologist as director, should be certified in both pediatrics and pediatric cardiology and fully trained in the radiology of cardiac imaging and radiation protection. It is recommended that the laboratory director have at least five years of immediate past experience performing cardiac catheterizations and angiographic procedures at a minimum case load

of 200 procedures per year. The director should be a skilled administrator, tolerant and supportive of the needs of the disciplines and departments that the laboratory serves.

Clinicians

Clinicians using the cardiac catheterization laboratory should hold certification from the Royal College of Physicians and Surgeons of Canada in cardiology, internal medicine, pediatrics or radiology. In the latter cases the physicians must have had further training in cardiology.

Technologists

At present, there are no recognized courses available for these technologists in Canada. In most laboratories, individuals are trained on site. Many have backgrounds in other technological fields.

Nurses

The nurses involved in the cardiac catheterization laboratory should be registered in the province and have a year of general nursing experience. They should have a minimum of six weeks in-house training before assuming full professional responsibility. Basic nursing functions include observation of the patient, surgical preparation of the procedure site and administration of medications.

6.2 Continuing Education

Medical

The clinical director and physicians with privileges should engage in regular continuing education to enable them to keep abreast of new knowledge and techniques in the area of heart catheterization. The attendance at a minimum of one national or international meeting per year is highly desirable. For desirable. For individuals working in a small non-

university unit, it is advisable that at least one week per year be spent in a larger unit for ongoing education with a practical emphasis.

Nursing and Technological Staff

There should be a program of continuing in-service education for laboratory staff which should consist of training in electrophysiology, radiology, nursing techniques and diagnostic techniques. Maintenance and enhancement of skills should be encouraged by contact with other technologists in the cardiovascular fields as well as by review of the current literature. Key personnel should be given the opportunity to visit other centres to enable them to update their knowledge. They should be encouraged to take part in the national and international organizations of their respective groups.

General: All Staff

All members of the catheterization teams - physicians, nurses, and technologists - must maintain current certification in cardiopulmonary resuscitation. Certification in advanced cardiac life-support is desirable for all, but mandatory for at least one member of the team.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

Supporting services should include:

Biomedical engineering services: It is ideal to have biomedical technicians available on the premises to deal with equipment failures occurring during procedures. It should also be the responsibility of the biomedical technician to make ongoing checks of the electrical safety of the unit on a monthly basis.

Blood gas analysis service: Results of the analysis should be immediately available to the clinician during the procedure. This requires that the equipment be in or close to the cardiac catheterization laboratory.

Resuscitation team: This team should be immediately available upon request.

A cardiac surgical facility: The services of the cardiac surgical unit should be readily available to the cardiac catheterization laboratory, as outlined previously.

Regional transportation system: In those units that fulfill a regional role, working arrangements must be established with the regional transportation system.

Radiology consultation: This service should be readily available.

Non-invasive cardiac diagnostic services: All cardiac catheterization laboratories should have access to these facilitites in addition to cardiovascular nuclear medicine and stress testing.

Neonatal Intensive Care Unit: This service is required if emergency investigations are performed on newborn infants.

Specialized central supply services.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

The space requirements will depend upon the scope and range of clinical and research activities provided by the laboratory. Space should be provided for the following functions:

8.1 Administration and personnel facilities, including office space for the clinical director, administrative activities, secretarial space, a receiving area, appropriate locker rooms, change facilities and washrooms.

8.2 Cardiac catheterization procedure room

Each room should be 55.7 m^2, with no dimension less than 6.1 m. The size of the room should be adjusted upward depending upon the type of radiographic equipment being used. The ceilings, walls and floors of the procedure room should meet the appropriate standards for design and construction, including the specific requirements regarding radiation safety. The doors should be of adequate size, not only to admit a patient on a stretcher but to allow for the transport of a patient who may require specialized equipment, such as the balloon pump.

The control room of appropriate size, i.e. at least 9 m^2, would be located directly adjacent to the cardiac catheterization laboratory. The size should be adjusted upward, depending upon the size of the control panels for the radiographic equipment. If at all possible, the hemodynamic monitoring equipment should also be located in this room to allow better protection of the personnel against radiation.

Computer flooring is recommended for the control and equipment room. This provides for, and gives ready access to, cabling necessary for modern X-ray equipment. Adequate cooling and ventilation is essential.

8.3 Special attention should be directed to required space for the following:

- clean and dirty utility rooms
- equipment storage, maintenance and repair.

8.4 Equipment and materials: Adequate facilities should be provided in the procedure room for the storage of sterile and sensitive equipment such as cardiac catheters and transducers.

8.5 The computation room should be provided with sufficient space to allow adequate analysis of graphic data by technical personnel.

8.6 Cine developing facilities - shared or dedicated.

8.7 Cine projection facilities: Although these need not be located in the actual laboratory, they should be located nearby, and should include sufficient space for storage of films, as well as a suitable projector and screen.

8.8 Location of the cardiac catheterization laboratory: Location of the suite close to the cardiac surgical suite allows for the transfer of patients from the cardiac catheterization laboratory to the operating room with a minimum of transportation, and allows optimum use of the facility in an emergency situation. Where a choice exists, ready access from the Emergency Department and the CCU would be desirable.

8.9 Facility for physical examination of patients: A room or curtained-off cubicle should be provided for use by clinicians associated with the department.

8.10 Additional Space

The following facilities must be available for a functional operating laboratory but may be shared with other services:

- Reception, secretarial, and transcribing resources
- Waiting and holding area
- Preparation room, recovery, and observation area
- Darkroom and processing facilities
- Blood gas chemistry laboratory
- Viewing and reporting areas

- Film file room
- Conference room
- Library and study room
- Teaching aids and file
- Record filing area
- Office space for staff, residents, and allied health personnel
- Doctors' and nurses' dressing rooms
- Toilet facilities
- Storage space for general supplies, linen and chemicals
- Vented area for radioactive material and gases

9. EQUIPMENT

Basic equipment requirements of a cardiac catheterization laboratory would include:

9.1 An image intensification system, which would allow for fluoroscopy and the recording of cine angiograms in multiple oblique projections, preferably inaxial projections. A suitable video tape recorder is necessary for immediate playback. In pediatric facilities, biplane angiographic equipment is optimal.

9.2 Monitoring equipment, which would provide for the recording of a minimum of two ECG channels and two intravascular pressures, dye dilution curves or thermodilution curves. The degree of sophistication of this equipment will vary from laboratory to laboratory depending upon the type of investigations performed.

A repeater oscilloscope, remote from the recording apparatus but located as near as possible to the fluoroscopy video monitor. Similarly, a remote video monitor in the field of view of the polygraph recorder operator is desirable for coordination of functions.

9.3 Equipment for cardiopulmonary resuscitation, including a defibrillator in each procedure room, as well as appropriate equipment for artificial ventilation.

9.4 Equipment for delivery of oxygen.

9.5 Suction equipment.

9.6 Blood gas analysis apparatus capable of determining pH, PCO^2, PO^2. This need not be located within the suite.

9.7 Variety of devices for collecting and analyzing expired gases.

9.8 Computer data processing: Dedicated or time-shared computers are being used in some laboratories for on- or off-line computation of various physiologic parameters.

The equipment and the degree of sophistication of the equipment will vary from hospital to hospital, depending upon the particular needs of that institution. Aside from considerations of obsolescence, cardiac catheterization laboratory equipment has a limited life-span, depending on the clinical requirements of the unit and on the case load. Although the rates of obsolescence varies between pieces of equipment, the life span of equipment is between five and 10 years. The actual replacement of specific items of equipment within this period should be evaluated by review related to internal use and technologic developments.

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

Close geographic relationships are desirable between the Cardiac Catheterization Laboratory and the cardiac care unit and cardiac surgical unit.

PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY

PREAMBLE

Percutaneous transluminal coronary angioplasty (PTCA) is a relatively new way of revascularizing coronary arteries obstructed by atherosclerosis. Since first being performed in 1977, it has become available in most urban areas in Europe and North America. It is clearly effective in reducing discrete stenoses in one or more coronary arteries, and its advantages lie in minimal patient discomfort and disability, and reduced hospital stay when compared to aorto-coronary bypass surgery.

Not every catheterization laboratory will find it suitable or desirable to perform PTCA. The requirements for starting a coronary angioplasty program are discussed below. It is, however, desirable that PTCA as a form of treatment be available in all urban centres to the extent that numbers of patients require it.

The requirements for a laboratory performing PTCA, both technical and in terms of personnel, are more exacting than those for cardiac catheterization. The laboratory must have superior X-ray imaging facilities for the proper positioning of angioplasty catheters in the coronary arteries. The medical, nursing and technical personnel must have considerable experience and expertise in performing and interpreting coronary angiography. There must be immediate access to cardiac anesthetic and surgical services when required. Finally, a sufficient population of patients suitable for PTCA must be referred to the laboratory to allow the staff to acquire and maintain the skills necessary to perform successful PTCA. Each of these requirements will be discussed separately below.

GUIDELINES

1. PATIENT LOAD AND DISTRIBUTION OF UNITS

A desirable case load for a laboratory beginning to perform PTCA would be at least one case per week. If ten per cent of patients considered suitable for coronary bypass surgery would be anatomically appropriate for a laboratory starting PTCA (the proportion rises with experience), then 500 such cases per year would be necessary to yield the above number. For the average laboratory, perhaps one-half of patients undergoing study for chest pain might be candidates for revascularization procedures. Thus, a laboratory would have to perform approximately 1000 coronary angiograms per year to have the necessary number of patients to initiate a coronary angioplasty program. An alternative would be a total referral base of at least this size, including patients having coronary angiography at another centre where PTCA would not be available. Again, the larger the workload in coronary angiography, the greater the body of experience and skill that can be directly applied to the performance of PTCA.

2. BED REQUIREMENTS

Although PTCA procedures are carried out in cardiac catheterization laboratories (page 77), in-patient beds are required for patient management and supervision for a minimum of 24 hours following the procedure, and should be readily available.

3. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

See Cardiac Catheterization Laboratories (page 78).

4. STAFFING CONSIDERATIONS

(To be read in conjunction with Cardiac Catheterization Laboratories, pages 75 to 91).

Two physicians are optimal for performing a PTCA using a steerable guidewire system. One may be learning the procedure, but the principal operator must be an experienced angiographer. Several years' of experience with coronary angiography, and a firm knowledge of its problems and pitfalls along with a clear understanding of coronary anatomy and the ability to conceive of it in three dimensions are necessary for the angioplasty operator. A demonstration course in PTCA serves as an introduction but a minimum of fifty supervised procedures would be best before independent angioplasty is allowed - probably twice that many are necessary before maximal skills are obtained. A good grounding in the clinical treatment of coronary disease is necessary as well.

Nurses and technologists must also be experienced in coronary angiography and conversant with coronary anatomy, to understand the procedure, monitor its progress and to recognize potential problems. Scrub nurses must be trained and supervised in the preparation of the catheters, the pneumatic syringe and the dilating balloon. Nurses must take part in the maintenance of a bubble and clot-free catheter system. At times, injection of contrast medium or nitroglycerin into the coronary tree, inflation of the syringe or manipulation of the guidewire may be delegated to experienced and specially trained nurses under direct supervision.

For simultaneous pressure measurement from the guiding and dilating catheter tips, meticulous technical preparation of the catheters, y-connectors, manifolds, manometric tubing and transducer domes is needed. The technical hurdles are greater than those encountered in routine diagnostic studies when simultaneous equisensitive measurements are made, due to the number of connections and the size of the components. Nursing and technological skills are of great importance here so that the procedure will not founder on such technical details.

5. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

Cardiac surgery: Dilatation of a coronary artery stenosis carries with it the risk of acute occlusion of the vessel. Unless collaterals are excellent there is potential for infarction with its attendant complications. Thus the need for access to emergency cardiac surgery is much more acute than for the exclusively diagnostic laboratory. The operating suite in this case must be adjacent to allow transfer of a sick patient with minimal delay. A fully equipped and staffed operating room must be available when coronary dilatation is carried out. A cardiac surgical and anesthetic team must be readily available and aware of the procedure. Most of the mortality from PTCA is related to inordinate delay in beginning bypass surgery after coronary occlusion. However, with increasing experience and collaboration between the catheterization and surgical teams, it is possible to achieve an emergency surgical rate of 5% and a resultant infarction rate of 2%. For the experienced cardiac surgical team, no special preparation of the PTCA patient for the surgical contingency is necessary other than typing and antibody screen of the blood beforehand.

Other departments and services will be as listed under Cardiac Catheterization Laboratories (page 87).

6. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

Please refer to Cardiac Catheterization Laboratories (page 86).

7. EQUIPMENT

(To be read in conjunction with Cardiac Catheterization Laboratories, page 90).

The enhanced technical requirements for the performance of PTCA largely relate to the X-ray imaging system. To begin with, more anatomic detail of the coronary arteries is demanded for PTCA than for bypass surgery. Thus the imaging and developing system must provide excellent resolution, freedom from distortion and a full contrast scale. The image intensifier tube must have a complete range of transverse rotation, along with cranial and caudal angulation, in order to demonstrate all the coronary segments free from overlap and with a clear view of eccentric lesions.

For the dilatation procedure itself, the need is for a superior video imaging chain which will allow clear visualization of even small branches of the coronary arteries. This will facilitate the passage of the catheter and guidewire to the proper branch with minimal time and morbidity. Appreciation of the change in the angiographic anatomy after dilatation and before the procedure is ended also requires an excellent video image. A video monitor should be positioned close to the operators to allow such detail to be clearly seen. A second video tape recorder will allow recording of a marker catheter positioned across the stenosis, and an additional monitor is needed to display such a static image (freeze-frame) throughout the procedure in a place where it can be seen by the operators.

As more coronary angioplasties are performed as an intervention in acute coronary events, the diagnostic and therapeutic procedures are necessarily combined. If possible, developing the cine film immediately in an adjacent film processor will allow review of the cine image before dilatation begins. If this is not possible (e.g., after normal working hours), then an excellent video image becomes especially important in such cases.

Independent biplane image intensifiers will reduce the length and difficulty of many PTCA procedures by allowing rapid visualization of the catheter and guidewire in complementary projections without moving the patient.

A stable, equisensitive dual pressure recording system is also required.

8. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

Close geographic relationships are desirable with the cardiac care unit.

9. ASSESSMENT OF PERFORMANCE

It is important that the selection of patients for and assessment of results from PTCA be as careful as they would be for cardiac surgery. Candidates for angioplasty should have their coronary angiographic films and pertinent clinical data reviewed by a panel of those cardiac specialists involved in PTCA (including a cardiac radiologist if available). This will promote consistency in the selection of patients for the procedure with a good chance of success and a reasonable risk.

The early and late results of the procedure should be documented by the director of the catheterization laboratory. Complications attributable to the procedure should be logged as they are for (but separately from) diagnostic cardiac catheterization. Exercise testing with a standard protocol should be routinely carried out early and late after the procedure. Exercise thallium scintigraphy has been found to be particularly helpful in documenting recurrent stenosis after successful PTCA. Each centre should assess its own late results angiographically until a satisfactory rate of sustained improvement in vessel patency is assured. With careful selection of patients and a modicum of experience a primary success rate of 80 per cent or more and restenosis rate of not more than 25 per cent are attainable.

The mortality from PTCA in patients with single vessel disease should be less than 1 per cent. In patients with multivessel disease, significant left ventricular dysfunction or previous coronary bypass surgery,it may be slightly higher than that. The accepted rates for emergency bypass surgery and myocardial infarction have been alluded to. Rates of other cardiac or vascular complications should not differ significantly from those of diagnostic catheterization. The catheterization laboratory director should monitor these rates and should review with the physicians involved, and on a regular basis, any untoward events that occur in the course of PTCA.

ELECTROPHYSIOLOGY LABORATORIES

PREAMBLE

An electrophysiologic laboratory is a facility designed, staffed and equipped to provide invasive electrophysiologic studies of the heart.

Electrophysiologic laboratories have grown out of the increasing knowledge of the nature of cardiac arrhythmias and their importance in cardiac mortality. With the advent of programmed electrical stimulation of the heart it is now possible to study the properties of the conduction system in the heart and to define the site of origin and mechanism of both supraventricular and ventricular tachycardias. The recent advent of mapping-guided surgery in patients with both SVT and VT has rendered the precise localization of tachycardia circuits important in the therapy of patients with tachycardias. Furthermore, programmed stimulation in patients with Wolf-Parkinson-White syndrome has allowed not only the accurate localization and knowledge of the conduction properties of the accessory pathway, but also has allowed electrophysiologists to predict those patients who might be at risk of sudden death.

The development of electrophysiologic laboratory services in hospitals, like those of general cardiac catheterization laboratories, should be related to community need and the availability of other specialized cardiologic services. Because the installation of such laboratories is expensive and the availability of skilled personnel limited, these laboratories should be limited to centres where the services can be justified by a large patient load and by the teaching and research activities in such facilities.

GUIDELINES

1. PATIENT-LOAD

Electrophysiologic facilities should only be set up in institutions where a case load of approximately 100 studies per year can be expected.

2. BED REQUIREMENTS

Although patients with life-threatening arrhythmias undergoing trials of medical therapy require continuous in-hospital monitoring, for the majority of patients undergoing electrophysiologic study such intensive monitoring is not required. A large number of these patients with conduction problems, sinus-node disease or supraventricular tachycardias which are not life-threatening require only venous catheterization during their electrophysiologic study and may be reasonably studied as out-patients providing an appropriate day care facility is available for observation for at least four hours following the procedure.

3. RECOMMENDED DISTRIBUTION OF UNITS

For the electrophysiologic laboratory to generate 100 studies per year, a population base of about 500 000 is required. Although immediate cardiac surgical availability within the same institution should not be a requirement, because of the value of surgical therapy in recurrent ventricular tachycardia and in Wolff-Parkinson-White syndrome, a relationship with an institution providing these services should be established. Because of the developmental nature of these services and because of the important teaching and research functions of the electrophysiology laboratory, such units should only be located in active teaching institutions with cardiology training programs.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Clinical Direction

The electrophysiology laboratory must be under the direction of a cardiologist who is adequately trained in all aspects of cardiac care.

4.2 Administration Direction

In situations in which the electrophysiology laboratory is a separate room from the other cardiac catheterization labs, the director of the electrophysiology lab should be responsible for its own overall administrative direction. In situations in which the electrophysiology laboratory is part of the general cardiac catheterization facility, responsibility for administration may be under the direction of the cardiac catheterization laboratory director in cooperation with the director of the electrophysiology laboratory.

4.3 Policies and Procedures

Policies governing the electrophysiology laboratory should be developed by the clinical director in consultation with the hospital's administration and cardiologists using the laboratory, and will parallel those developed for the cardiac catheterization laboratory (page 78). These policies should include:

- Policies related to clinicians performing electrophysiology studies: It is essential that the use of the electrophysiology laboratory be limited to those physicians especially trained in all procedures.

- Policies regarding intra- and inter-hospital referral, management and transfer of patients for investigation.

- Policies regarding continuing evaluation: These policies should include analysis of case material, analysis of the technical aspects of the procedures, the quality of data and complications. Evaluations should be reviewed with relationship to other centres.

- Clinical and administrative lines of authority: These policies should define the relationship of nurses in the area to nursing administration in the hospital, as well the relationship of technologists to the unit and to other technical services in the hospital.

- Policies regarding identification and management of procedural complications

- Responsibilities of staff: Policies should be clearly defined regarding the roles, functions, and relationships of all members of the unit, medical, nursing, technological and other staff. In addition to a statement on policies, a procedural manual of the unit services should be developed and maintained. In general, this should include indications for electrophysiological studies, appropriate techniques as applied to that laboratory and an outline of the procedures to be followed during complications.

- Policies regarding development of the annual budget, and the purchase of equipment and proper maintenance

- Scheduling and conducting of regular conferences attended by all laboratory personnel to review data for quality, resolve interpreter problems, announce discussed decisions regarding patients studied, etc.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Introduction

The smooth functioning of a laboratory requires the availability of skilled professional and technical personnel. In addition to appropriately trained physicians, this includes nursing personnel, special procedure, radiologic and electronic technologists, and other support staff. It should be recognized that, in order to provide high quality data for interpretation, the electrophysiology laboratory must have an ongoing program for maintenance and updating of recording equipment and a close relationship with the institutional Department of Biomedical Engineering.

5.2 Clinical Director

The clinical director of the electrophysiology laboratory should be chosen from among appropriately trained physicians, and duties and responsibilities should be clearly outlined as noted in sections 4.1 and 4.2.

5.3 Technical Staff

A minimum of two persons providing technical skills should be available for the operation of any unit. These may be either technologists or specially trained nurses. The responsibility of the technical staff would be to provide constant monitoring of electrocardiographic and physiologic parameters as well as operation of polygraph recorders and the operation of the stimulation unit.

5.4 Registered Nurses

At least one registered nurse should be available as staff in the electrophysiology laboratory, and in particular to supervise sterile techniques and administration of drugs. The registered nurse participates in observation and nursing care of the patient during the electrophysiology procedure, and

appropriately responds to all patients' needs in any emergency that may occur. The nurse must be familiar with the overall function of the laboratory and be in a position to influence the efficiency and safety of procedures.

5.5 Radiology Technologist

A radiology technologist should be available for proper utilization of radiology equipment necessary for catheter insertion.

5.6 Other Staff

Appropriate ancillary staff such as cleaning and clerical staff should be provided as required.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial qualifications:

6.1.1 Clinical Director

The director should be a cardiologist with certification in cardiovascular medicine and with specialized training in electrophysiology. This training should include at least one year of specialized training in the field of cardiac arrhythmias and electrophysiology, in an active electrophysiologic laboratory performing at least 100 electrophysiologic studies per year. The clinical director should be able to supervise educational and research programs. Current ACLS certification or equivalent is necessary.

6.1.2 Clinicians

Clinicians using the electrophysiology laboratory should hold certification in cardiology from the Royal College of Physicians and Surgeons of Canada and must have appropriate training in elecrophysiology, including at least one year in an active electrophysiology laboratory after the completion of general cardiology training. Current ACLS certification or equivalent is necessary.

6.1.3 Technologists

Since there are no recognized courses available for these technologists in Canada, laboratory technologists are trained on site. The technologists must have certification in basic cardiac life support, and certification in advanced cardiac life support is desirable.

6.1.4 Nursing Staff

Nurses involved in the electrophysiology laboratory should be registered in the province and have at least one year of general nursing experience. Background experience for the nurse should include critical care and/or CCU experience with special knowledge of cardiovascular medications and experience in vascular instrumentation. The nurse should maintain certification in advanced cardiac life support.

6.2 Continuing Education

6.2.1 Medical Staff

The clinical director and cardiologists performing electrophysiologic studies should engage in regular activities in continuing education to enable them to keep abreast of new knowledge and techniques in the area of electrophysiology. The attendance of a minimum of one national or international meeting per year is highly desirable.

6.2.2 Nursing and Technological Staff

A program of continuing in-service education for laboratory staff should exist and consist of continued training in electrophysiology and diagnostic techniques. Key personnel should be given the opportunity to visit other centres and attend conferences. They should be encouraged to take part in national and international organizations of their respective groups.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

7.1 Biomedical Engineering:

Because of the nature of electrophysiologic laboratories, biomedical technical services must be available on the premises at all times to deal with equipment failure and to ensure adequate maintenance of electrical safety on at least a monthly basis. As well, the biomedical engineering services should be responsible for in-house modification of equipment.

7.2 Resuscitation Team

This team should be immediately available upon request.

7.3 Cardiac Diagnostic Facilities

Cardiac catheterization and non-invasive laboratories should be available within the institution to facilitate prior studies of cardiac anatomy and function. Specialized cleaning, refurnishing and sterilizing facilities are necessary.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

The space requirements will depend upon the range of clinical activities provided. In the majority of instances the cardiac catheterization laboratory (suite) will be the site of electrophysiologic investigations. Otherwise this laboratory resembles a cardiac catheterization laboratory with additional space provided for storage of recordings and magnetic tapes.

9. EQUIPMENT

Basic equipment requirements of an electrophysiology laboratory include:

- Image intensification system
- Recording equipment

Facilities should be at the catheter table for switching and preamplification. All cable connectors must be shielded for protection from 60 cycle per second AC interference. Appropriately designed amplifiers should be provided. Facilities for FM recording for permanent storage of intracardiac signals should be provided, in addition to a multi-channel hi-fidelity polygraph. Monitoring equipment should be mounted such that one monitor displays, in real time, the electrocardiogram in clear view of the catheterizing physician. A second monitor should be in view of the technologist performing the stimulation and recording functions. Appropriate stimulation equipment should be available. Equipment for cardiopulmonary resuscitation including a defibrillator, appropriate equipment for artificial ventilation and intubation must be available for each procedure room.

III TREATMENT

III TREATMENT

CARDIAC CARE UNITS

(CORONARY CARE UNITS)

PREAMBLE

Hospitals for many years have segregated patients requiring intensive monitoring and specialized care. Cardiac Care Units, (CCU) are intended for this purpose. In larger hospitals, however, it may be useful to provide an intermediate step between the CCU and the normal acute care nursing unit, without increasing the total number of beds devoted to cardiac care. For this reason these guidelines describe both the CCU and the Intermediate Cardiac Care Unit. The latter will be found in larger facilities where such differentiation may be warranted.

A Cardiac (Coronary) Care Unit is a type of unit that is specifically designed, staffed and equipped for the continuous observation, monitoring (hemodynamic and/or electrocardiographic) and treatment of patients with:

1. Acute coronary heart disease

The term "acute coronary heart disease" is used here to cover the entire spectrum of acute ischemic heart disease. It excludes stable angina pectoris. It includes all "components" of the intermediate coronary syndrome, i.e. unstable angina pectoris, acute coronary insufficiency, impending myocardial infarction and acute myocardial infarction.

2. High risk arrhythmias (regardless of etiology)

3. Certain types of acute non-ischemic heart disease which, because of the presence or risk of complications such as arrhythmias, myocardial failure, pericardial effusion, etc., require the special services of the unit.

The term "cardiac care unit" conveys more accurately the broad cardiac functions currently provided by most coronary care units. For this reason, and in keeping with increasingly popular usage, the term "cardiac care unit" is used instead of "coronary care unit". The abbreviation "CCU" is retained for both terms.

The concepts on which cardiac care is based include the following:

1. All patients with acute coronary heart disease are at high risk of developing arrhythmias and other cardiovascular and pulmonary complications.

2. All of these complications may be detected by monitoring of cardiac rhythm, skilled observation and, where indicated, hemodynamic monitoring.

3. Early detection of complications permits early treatment, with resulting decreased morbidity and mortality.

4. If cardiac arrest occurs, resuscitative measures are more likely to be successful if administered in an emergency cardiac care setting.

Emergency cardiac (coronary) care must be provided in all active treatment hospitals. However, the scope of cardiac care provided will depend on factors relating to the hospital, the community and the region.

In hospitals too small to operate a cardiac care unit (CCU) the mode of delivering cardiac care will depend on staff competence and availability, consultative links with existing centres and the proximity to CCUs within the district or region.

Should such a hospital have an intensive care unit, cardiac care for small or marginal case-loads is better provided within the ICU, where the specific cardiac care requirements should be made available. (see Intensive Care Unit Guidelines)

Regardless of the case load, the decision to establish a new CCU must be made in the context of community needs and resources. It should be recognized that for CCUs with sufficiently large patient-loads and medical and nursing staff capabilities, new methods of investigation and treatment can be introduced more readily. In this context, the existing loads may continually thwart the development of more sophisticated and comprehensive cardiac care in that community.

Despite notable advances in the management of acute coronary heart disease, particularly in the detection and management of arrhythmias, many problems remain. There is currently marked interest in a number of old and new aspects of investigation and management, which include the following:

> pre-hospital coronary care; hemodynamic monitoring; non-invasive technology; prevention of myocardial infarction; quantification of myocardial infarction; management of the intermediate coronary syndrome, prevention and treatment of cardiogenic shock; the role of emergency coronary artery surgery; intermediate coronary care, and home management of selected patients with acute myocardial infarction.

It is evident from the above that, despite the 23 years since the opening of the first CCU in 1962, significant changes in the guidelines are to be anticipated in the future.

GUIDELINES

1. PATIENT-LOAD

1.1 Eligible Patients

- All patients with acute coronary heart disease.
- All patients with life-threatening arrhythmias.
- Selected patients with acute non-ischemic heart disease requiring continuous observation, ECG monitoring and possibly hemodynamic monitoring for adequate management.

1.2 Minimum annual case load

Although patients with a variety of cardiac conditions may be eligible for admission to the CCU, its principal role is the management of acute coronary heart disease. An annual caseload of three hundred (300) to four hundred patients (400), which will include two hundred (200) patients with acute coronary heart disease, is sufficient justification for a CCU separate from the ICU. An approximation of potential case load of acute coronary heart disease may be obtained by multiplying the annual number of proven cases of acute myocardial infarction by 1.5.

2. BED REQUIREMENTS

A number of factors influence bed requirements for the cardiac care unit. These include: the degree to which management of cardiac problems other than acute coronary heart disease is a function of the unit, average length of stay as affected by admission criteria (treatment of the patient with acute myocardial infarction may necessitate a stay in the unit of four to five days or longer if complications ensue, as opposed to other problems which may be managed in one or two days) and the availability of satisfactory monitoring facilities outside the CCU. An intermediate care (progressive care) unit (ICCU) allows safe transfer of many patients from the CCU at an

earlier date. It also allows some patients who do not have acute coronary heart disease, but who require ECG monitoring, to be admitted to the ICCU at times when the CCU is filled with higher priority patients.

The following criteria for estimation of bed requirements may be used because of the net balancing effect of a number of the factors listed above.

Criteria applied in estimation of bed requirements:

- 65 patients per bed per year
- average length of stay (A.L.S.) - three to five days.
- occupancy - 80 per cent

A minimum case load of 200 patients per year can be accommodated in a four-bed unit. This is the minimum practical size for a cardiac care unit. The optimal size for a CCU (based on case-load) is in the range of six to 10 beds.

A CCU of fewer than four beds is inefficient in staff utilization, excessively costly to operate, and would be justified only in exceptional circumstances.

Where the minimum case-load is not met, cardiac care is better provided in the intensive care unit, where the specific requirements for cardiac care should be made available.

3. RECOMMENDED DISTRIBUTION OF UNITS

All active treatment hospitals must provide emergency cardiac (coronary) care, but relatively few hospitals require a cardiac care unit.

The question of need for a CCU is raised by demonstration of a minimum case load and adequate internal resources. However, the situation should not be

created where a number of CCUs compete for marginal or small case loads. The final decision to develop a CCU should be based on community and district needs and resources.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Medical Direction

The governing board of the hospital should appoint a medical director of the unit on the recommendation of the medical advisory committee. The medical director should be a certified cardiologist or internist, and should be supported by designated assistant physicians to provide constant coverage for daily rounds and emergency calls.

The patient's own physician may be involved in the care of a patient admitted to a cardiac care unit, but the unit's medical director must have the final authority in the admission, management and discharge of all patients.

A cardiac care unit committee, composed of representatives of the medical, nursing, allied health and administrative personnel concerned in this area, should be formed to review utilization, discuss problems, seek solutions and make recommendations to the medical director of the unit.

4.2 Policies

Policies should be clearly defined in writing and include under general headings the criteria for admission, management and discharge.

(See also Appendix I, "Guidelines for Policies and Procedures for Special Services in Hospitals").

4.3 Responsibilities of Staff

Medical

The unit's medical director will coordinate the multidisciplinary or team approach for therapy and care. The policies should clearly define, in writing, that the unit's medical director or his designated assistant is, at all times, finally responsible for the therapeutic management of the patients.

Nursing

There should be written policies delegating authority, in situations where immediate consultation by the unit's medical director or his assistant is not possible, for nursing personnel to perform certain procedures which have been approved by the board of the hospital and the appropriate provincial authorities.

Other Staff

The duties and responsibilities of all other staff also should be clearly defined in writing.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Medical Staff

- Medical director of unit, designated by the governing board
- At least two designated physicians for delegation of emergency responsibilty
- Attending staff
- Resident and intern staff, if available
- Twenty-four-hours/seven-days-a-week coverage

5.2 Nursing Staff

Nursing staff requirements are dictated by the physical facilities, the medical program and the acuity of the patient's illness. On the average, 12 worked nursing-hours are required per patient-day. However, the actual number of hours will be dependant upon patient classification.

A minimum of two specially-trained CCU registered nurses should be on duty at all times, with adequate back-up staff.

5.3 Other Staff

This will vary with the size of unit and type of patients treated.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Medical Staff

The medical director of the unit should be a cardiologist or an internist with certification in the specialty. Attending staff may include family physicians as well as specialists, depending on the policy of the unit. Family physicians intending to provide patient care in the unit should be required to have taken post-graduate courses in relevant aspects of cardiology and be certified at the ACLS level or equivalent.

Nursing Staff

The head nurse should have a minimum of a baccalaureate degree, and additional preparation in cardiac-care nursing from an approved educational institution.

The nurse-educator is a nurse with a minimum of a baccalaureate degree, preferably in nursing, from an approved educational institution, and with a minimum of one year's experience in cardiac care, and should be assigned to the unit on a full- or part-time basis. She should be certified to teach BCLS and ACLS.

A clinical specialist with a master's degree in cardiovascular nursing would be desirable in hospitals with teaching facilities. In other hospitals this specialist could be shared with other units.

The registered nurses should have special preparation in cardiac-care nursing, BCLS certification and six months' experience in general nursing. One nurse with ACLS training should be available in the hospital at all times.

Other Staff

Specific training in their field of activity.

6.2 Continuing Education

Medical Staff

Medical staff should attend post-graduate courses, clinical conferences and seminars, and should visit special centres. They should play a major role in facilitating programmed instruction, audio-visual teaching and in-hospital courses for their staff.

Attending staff should attend a minimum of one post-graduate course per year.

Nursing Staff

The head nurse and nurse educator should be required to attend at least one cardiac-care or critical-care conference, seminar, workshop or advanced cardiac-care nursing course annually. Registered nurses should be encouraged to attend conferences, seminars, or workshops, in addition to participating in a continuing in-services educational program. BCLSand ACLS training and recertification must be available.

Other Staff

Hospital-based educational programs, seminars and workshops should be provided. BCLS training and recertification should be available, particularly for nursing support staff.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

- Anesthesiology
- Biomedical engineering (availability of this service from off-site source will suffice)
- Blood gases
- Dietetics
- E.C.G.
- Laboratory
- Non-invasive cardiac diagnostic services, such as myocardial imaging and electrocardiography
- Pharmacy
- Psychiatric services
- Radiology image-intensifier for insertion of pacing and other catheters
- Regional emergency transportation system with communication system for mobile life-support care (emergency cardiac care, pre-hospital coronary care)
- Respiratory therapy service
- Social service

Certain hospitals may establish special teams, such as cardiac-arrest teams or interhospital transfer teams, as necessary.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Direct Patient Care

To provide privacy and sound control, patients should be accommodated in single rooms separated by full walls. Each room should have a minimum net floor space of 17 m^2 and should not be less than 4.6 metres in length or 3.6 metres in width.

NOTE: During cardiopulmonary resuscitation the head of the bed is usually pulled out approximately .915 metres from the wall to permit intubation and other acute respiratory support procedures. This .915 metres (three feet), plus the length of the bed, occupies

approximately 3 metres. At least another 1.22 metres (four feet) is required to allow staff, carts, portable X-ray equipment, etc., to pass the foot of the bed. Consideration should be given to the possible need to admit portable devices (or gamma camera) into areas for patients.

There should be a window in each patient's room, preferably with an outside view from the patient's bed. A cheerful decor is necessary. Although carpeting may be used in the corridors to reduce noise, a washable floor covering in the patients' rooms is preferred. A clock and calendar should be provided in each room, but located discreetly to one side out of the patient's main field of vision.

Preferably, each patient should be visible to the nurse in the central nursing station.

Lighting must be zoned within each room and controlled by individual light switches and, where required, solid state dimmer switches. This should permit: comfortable levels of lighting for the patient's activities (reading, shaving, resting, etc.), night lighting for staff circulation while the patients are sleeping, and high intensity lighting for examinations and emergency procedures. It is a common error to have inadequate illumination at the sides of the bed and, in particular, at the foot of the bed. For some procedures requiring high intensity illumination for the patient's entire body, it should be noted that the head of the bed may be out approximately one metre from the wall.

The unit should be located away from microwave ovens, large motors, etc. The room should be equipped with adequate isolated electrical circuits, an independent power source and controls for ventilation, temperature and humidity.

Bedside commodes are required for patients who are not ambulatory (provided that bedside flush toilets are not available). The area should be able to be curtained off to provide privacy when the door is opened.

A special-procedures room may be required for larger CCUs and in smaller units where individual patients' rooms are of marginal or substandard dimensions and not subject to correction, where such highly specialized techniques as intra-aortic balloon counterpulsation are done.

8.2 Support Areas

Floor space is needed for: the unit's patients' toilet facilities; the central nursing station; supply and storage; resuscitative and supportive equipment; clean and soiled utility rooms; lockers for patient's clothing; staff conference room; family waiting room; partitions and internal circulation. In smaller units some of these areas may be shared with contiguous, compatible facilities such as the ICCU.

8.3 Components

- The area per bed that has been indicated includes the following:

- Staff lounge adjacent to the ward connected to the intercom and tied into the alarm system of the CCU. Toilet space. (18.5 m^2 net total)

- A sleeping room with shower and toilet for on-call doctors (close to the unit and located so that the unit's staff may enter and leave the unit without passing through the visitor's lounge). (9.30 m^2 net)

- Laboratory services as required.

- Portable X-ray equipment. Storage area, if required.

- Conference and in-service education room for all units, 9.48 m^2, or 1.58 m^2 per person net. For small units the staff lounge may be used for this purpose.

- Waiting room for relatives and other visitors, 9.48 m^2, or 1.58 m^2 per person net.

- Minimal support space of 9.30 m^2 net for equipment storage.

- Office space for unit director.

9. EQUIPMENT

Hydraulic intensive care or cardiac beds (electrically operated beds should not be allowed in the unit), wall blood pressure cuff at each bedside, ceiling rods for hanging I.V. solutions.

Individual bedside monitoring equipment:

- Electrocardiographic (ECG) oscilloscopic monitor

At central nursing station - monitoring equipment which includes:

- Heart rate meter with alarm
- Slave oscilloscope
- Direct writing ECG strip recorder

Resuscitation equipment

D.C. defibrillator with back-up defibrillator for breakdown. The back-up defibrillator must be immediately available but need not be restricted to the unit. One of the D.C. defibrillators should have a synchronizing circuit to permit synchronized as well as non-synchronized discharge.

Temporary transvenous pacemakers (2)

Emergency crash cart with adequate supply of usual drugs and emergency equipment (tracheostomy set, endotracheal tubes, laryngoscopes, airways, manual breathing bag and mask, cut-down sets, disposable syringes, needles).

Bed boards, piped-in oxygen and compressed air, equipment for oxygen administration for every bed.

Suction equipment and outlet for each bed.

Supportive Equipment

- 12-lead ECG
- Infusion pump(s) for intravenous drugs
- Respirator
- Venous and intra-arterial pressure catheters and meters (types employed will depend upon specific needs.)
- pH meter and blood gas equipment should be available within a support unit but need not be situated within the CCU.
- Ultrasonic stethoscope (useful but not essential)

For a large CCU only

- Portable image intensifier which is not necessarily restricted for use in the CCU
- Multi-channel recorder.
- Facilities for cardiac output determination.
- Assisted circulation apparatus. Technical support requirements of the intra-aortic balloon pump and its close association with coronary angiography and aortocoronary bypass surgery make this item feasible only for regional centres at the present time.
- Computer-assisted ECG monitoring (may be merited in special circumstances after a detailed review of the need for such equipment.)

For all units, equipment requirements should be determined by demonstrated need (which includes case load and proven value of the equipment) and the continuous availability of the level of staff

competence required to provide safe, reliable and efficient operation. If these requirements are met, needless duplication of major equipment items within a geographic area will be avoided.

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

The CCU should be located in close proximity to other departments that deal with cardiac care, i.e. the emergency unit, intensive care unit, the surgical suite, the catheterization laboratory and the medical ward where intermediate cardiac care is provided. Grouping of these units facilitates rapid transportation of patients from the other units; allows help to be summoned quickly from other units; expedites the assistance of CCU staff in cardiac emergencies that may occur in other units; enhances the continuity of patient-care; facilitates telemetric monitoring.

These departments should be located on the same floor to avoid the use of elevators.

If it is not possible to locate the CCU in close proximity to the departments listed above, a direct communication line should be installed between the CCU and these departments. If the units cannot be located on the same floor, the CCU staff and the resuscitation team should be provided with the capability of elevator override.

INTERMEDIATE CARDIAC CARE UNITS

PREAMBLE

An intermediate cardiac care unit (ICCU) is an in-patient unit that is designed, staffed and equipped to provide a level of cardiac care which meets the specific needs of patients who do not require, or who no longer require, the full range of services of the cardiac care unit (CCU). The ICCU differs from the CCU in that it is not designed, staffed or equipped to monitor or treat patients who are known to be hemodynamically unstable or at high risk of becoming so. In the ICCU, emphasis is placed on clinical observation and treatment, electrocardiographic monitoring, emergency cardiac care, patient-education, immediate patient-rehabilitation and initiation of individually planned, long-term rehabilitation.

Although the majority of patients in the ICCU have ischemic heart disease, a significant number have other cardiac problems; therefore, the term "Intermediate Cardiac Care Unit" is preferred to:

1. "Intermediate Coronary Care Unit" because many patients admitted to the unit have non-ischemic heart disease, and

2. "Progressive Care Unit, or Area" because "progressive care" applies only to patients with acute ischemic heart disease who are initially admitted to the CCU and later transferred to the ICCU.

The level of care provided in an ICCU is of benefit to patients with acute ischemic heart disease following treatment in the CCU, and can also serve as an area for definitive treatment of patients with cardiac problems, such as selected arrhythmias, pacemaker problems or acute congestive heart failure. The latter groups of patients require monitoring and clinical observation, but do not require the full range of CCU services.

If located in close proximity to the CCU, the ICCU can occasionally serve patients who need CCU care, but for whom CCU beds are not immediately available.

The range of cardiac services provided by an ICCU necessitates that the unit be planned and organized to meet the requirements of the following clinical objectives and activities:

1. For patients with acute ischemic heart disease:

- early detection of arrhythmias and prompt initiation of treatment;
- emergency cardiac care;
- weaning from a higher intensity of nursing care and monitoring;
- activation under clinical and electronic surveillance;
- comprehensive education of patient and family concerning disease process, risk factors, and modification of lifestyle;
- systematic assessment of potential for physical, mental and social rehabilitation;
- prescription of rehabilitation activities, both immediate and long-term.

2. For patients with non-ischemic heart disease:

- arrhythmia detection and analysis;
- prompt treatment;
- emergency cardiac care;
- other activities, where these apply, listed for patients with ischemic heart disease.

3. For other cardiac patients requiring more intensive cardiac nursing care other than that which may be available on the regular ward.

Potential benefits of a properly planned and organized ICCU.

1. To patients with acute ischemic heart disease:

- continuity of in-hospital care during the acute episode;
- comprehensive, individualized educational program;
- activation (resumption of ambulation and self care) under clinical and electronic surveillance. This would permit rapid, safe activation according to the capabilities and tolerance of each patient;
- institution of comprehensive cardiac rehabilitation based on an objective and systematic assessment of physical, mental and social potentials and limitations;
- reduction of anxiety and the restoration of confidence in the capability to resume customary activities.

2. To the hospital:

- more appropriate use of cardiac-unit beds;
- decreased length of stay in CCU beds;
- a possible reduction in the number of CCU beds;
- cost-effective use of hospital staff.

GUIDELINES

1. PATIENT-LOAD

1.1.1 From the CCU:

- patients with acute ischemic heart disease: After it has been established that the patient is hemodynamically stable and that acute myocardial infarction, if present, is stable, the patient may be transferred from the CCU to the ICCU.

- patients with non-ischemic heart disease who still require ECG monitoring and/or clinical observation, but who no longer require the other services of the CCU.

1.1.2 From the ward, emergency department or outside the hospital:

Patients who require clinical observation, ECG monitoring and other elements of cardiac care but not the full range of CCU services. This includes:

- patients with suspected or proven arrhythmias requiring assessment and treatment;

- cardiac pacemaker patients who have suspected problems, and those who require routine monitoring before and after pacemaker implantation or battery replacement.

1.2 Minimum annual patient load

If a CCU of at least six beds has been operating according to strict admission criteria with an occupancy rate of over 80 per cent, an ICCU is probably justified. Otherwise, the surveillance, education and rehabilitation activities of the ICCU may be provided by special arrangements in a regular nursing unit adjacent to the CCU.

2. BED REQUIREMENTS

If an ICCU is to be established, there is no formula currently available for estimating ICCU bed requirements.

An estimate of bed requirements may be obtained by a prospective or retrospective study of the number of patients treated in the CCU and regular wards who, according to the criteria discussed under patient-load above, would be eligible for admission to the ICCU.

The unit should be sized such that an average occupancy rate of over 80 per cent will be maintained. This also requires that there be policies and protocols specifically directed to identifying suitable patients and facilitating their rapid transfer to the regular wards.

3. RECOMMENDED DISTRIBUTION OF UNITS

Unless a CCU of adequate size is required (see Guidelines on CCU), an ICCU is not justified. In hospitals where patients with ischemic heart disease are treated but where an ICCU is not justified, some of the objectives can be met in a nursing unit adjacent to the CCU or ICU.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Clinical Direction

The clinical director of the CCU should be the director of the ICCU.

In smaller hospitals that clinical director of the CCU may be the director of the ICCU. In hospitals whose CCU has eight to ten beds, the clinical director of the ICCU could be another certified cardiologist or internist.

Management of patients admitted to the ICCU is generally the responsibility of the attending physician. The clinical director of the ICCU, however, must have final authority in the admission, management and discharge of all patients in the unit.

4.2 ICCU Committee

The cardiac care unit committee should serve the ICCU as well as the CCU and should include a member of the rehabilitation team. The committee should review utilization, discuss problems, seek solutions and make recommendations to the clinical director. During its review of the ICCU, the CCU committee should include the ICCU head nurse and those concerned with immediate and long-term rehabilitation of patients.

4.3 Policies, Procedures and Control

Policies should be clearly defined in writing and should include under general headings the criteria for admission, management, defined levels of patients' activity and discharge.

See Patient-load (p. 132) regarding admission and discharge affecting occupancy rate.

See also Appendix I, "Guidelines for Policies and Procedures for Special Care Units in Hospitals".

4.4 Responsibilities of Staff

Medical

The clinical director will coordinate the multi-disciplinary or team approach for therapy and care.

Although the attending physician is responsible for day to day management of patients, it should be clearly defined in writing that the clinical director or his designated assistant is at all times finally responsible for the therapeutic management of patients.

Nursing

In situations where immediate consultation by the attending physician or the clinical director is not possible, there should be written policies delegating authority for nursing personnel to perform certain procedures which have been approved by the hospital's board of trustees and the appropriate provincial authorities.

Other Staff

The duties and responsibilities of all other staff also should be clearly defined in writing.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Medical Staff

- Clinical director of unit, designated by the governing board.
- At least two designated assistants for delegation of emergency responsibility.
- Attending staff.
- Resident staff if available.
- 24-hour/seven-day-a-week coverage.

5.2 Nursing staff

A head nurse should be appointed to the unit. There must be at least one registered nurse on each shift who has experience and special preparation in cardiac-care nursing. The number of nursing personnel required will depend on the size and design of the unit, its proximity to another unit, the average patient census, the medical program and the individual needs of patients.

A ratio of one nurse to four patients has been found to provide a satisfactory level of patient care.

5.3 Other staff

This will vary with the size of unit and type of patients treated, but the services of a dietitian and rehabilitation staff are required.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Medical staff

Medical director - cardiologist or internist (with training in cardiology) - certification in specialty.

Attending staff - may include family physicians as well as specialists, depending on the policy of the unit. Family physicians should be required to take post-graduate courses in relevant aspects of cardiology.

Nursing staff

The head nurse must have special preparation in cardiac care nursing and preferably have a baccalaureate degree in nursing.

Registered nurses should have special preparation in cardiac care nursing.

Other staff

Specific training in their field of activity as related to cardiac care.

All staff should be certified in basic life-support (CPR) according to the standards of the Canadian Heart Association.

6.2 Continuing education

Medical staff

Attendance at one or more of the following is recommended: postgraduate courses, conferences, seminars, in-hospital courses, visits to special centres, and clinical conferences.

Nursing staff

- Competence in ECG monitoring in particular, and in cardiac care in general, should be maintained both by in-service education programs and by periodic rotation through the CCU.

- Attendance at post-basic courses in coronary care nursing, cardiac rehabilitation, refresher courses, seminars, workshops and at hospital-based education programs should be encouraged.

Other staff

In-service educational programs, seminars and workshops should be provided.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

CCU and its supporting departments and services, including dietetics, rehabilitation, social service, psychiatry.

It should be noted that non-invasive cardiovascular services in general, and the exercise ECG laboratory in particular, can be expected to have increasing utilization by the ICCU.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Location of ICCU

The ICCU should be located directly adjacent to the CCU. This permits immediate access to the services of the CCU, and facilitates the circulation of staff and the transfer of patients between the two units.

8.2 Direct patient care

8.2.1 Patients' rooms

It is not necessary that patients be visible from the nursing station.

It is preferable to accommodate all patients in single rooms, but a mix of single and double rooms is acceptable provided there is a minimum of 2 single rooms in the unit. The design features and space requirements for patient rooms described in 8.1 of the guidelines for the CCU apply equally to the ICCU and should be observed in both the single and double rooms of the ICCU. In double rooms, it must be possible to provide emergency cardiac care for one patient without encroaching on the other patient's space. Bed curtains must be so arranged that the patient and staff are screened off during emergency treatment.

8.3 Support areas

Floor space is needed for patients' toilet facilities, the central nursing station, supply and storage, resuscitative and supportive equipment, clean and dirty utility rooms, lockers for patients' clothing, staff conference room, lounge, partitions, internal circulation, etc. In smaller units, these spaces might be shared with compatible, contiguous units, such as the CCU.

8.4 Components

The area per bed includes the following:

- A staff lounge adjacent to ward connected to the intercom and tied into the alarm system of the CCU. Toilet space. (18.5 m^2 net total)

- A conference room for patient-relative teaching and in-service education is essential. A space allocation of 9.48 m^2 or 1.03 m^2 per person net is recommended. If dictated by limited space, shared use of a conference room outside the ICCU would be acceptable provided that the room is (1) close to and on the same floor as the ICCU (2) always available for the scheduled sessions of ICCU. Wherever it is located, the conference room must permit satisfactory telemetric monitoring. A 2-way communication system (intercom or direct line phone) between the nursing station and the conference room and an emergency alarm system are also basic requirements.

- For patients and visitors, a lounge with an emergency alarm.

- A minimal support space of 9 m^2 net for storage of clinical and educational equipment and materials.

Central Nursing Station

The central nursing station should be centrally located within the ICCU to facilitate patient-care.

Toilet facilities

Bedside commodes are required for patients who are not ambulatory (provided that bedside flush-toilets are not available). In either instance, the area should be curtained off to provide privacy when the door is opened. A washroom with toilet and basin should be available for all rooms, but may be shared by location between rooms where this is favored.

Some patients require being taken to the washroom by wheelchair, and all patients are at risk of having a cardiac arrest while in the washroom. Therefore, the doorway should be at least 76.2 cm wide, the door should slide or swing out, and the area around the toilet should be sufficient to allow easy extrication of the patient should this be necessary. There should be no locks on the washroom doors, and door signs should be provided to ensure privacy.

Bathrooms

Use of bathrooms will be affected by two considerations:

- most patients transferred from the CCU will be limited to bed baths for the first few days.
- most patients will be able to have a daily bath or shower - at least with assistance - by the time of discharge.

One bathroom per six to eight patients in the ICCU should be adequate.

Direct entry to the bathroom from the corridor is advisable for flexibility of use.

The bathroom should be of sufficient size to:

- accommodate a bench or chair without encroaching on the space at the side of the tub;
- allow a staff member, if required, to assist the patient in or out of the tub;
- allow easy extrication of the patient by two staff members in the event of an emergency.

To accomplish this, the net space at the side of the tub should be 1.2 m. x 2.0m., 2.4 m^2. A sliding door is preferred. If there is no alternative to the door swinging in, the door should be hung to permit easy removal from the outside.

Each bathtub should have a fixed shower head.

A thermostat that will prevent sudden and unexpected changes in water temperature is desirable.

An emergency alarm cord should be located so that it is accessible to the patient while in the tub. Electrical safety requirements for the area must be met.

Illumination should be adequate to allow detection of pallor or cyanosis. Ventilation should allow the staff member to assist the patient without being drenched by the high humidity, but at the same time, provide a comfortable environment for the patient.

It is to be emphasized that a few properly designed bathrooms will be much more useful and safer than a larger number of standard bathrooms.

Corridors

Progressive ambulation is an important function of the ICCU and this is generally initiated in the corridors of the unit. For this reason, illumination and decor are important considerations for the corridors as well as the patients' rooms and work areas.

A hand railing along the corridor walls and easy access to chairs will provide assistance and help to prevent over-exertion during the early stages of ambulation.

9. EQUIPMENT

Standard hospital beds with manually operated high, low and tilt adjustments are required. Electrically operated beds should not be allowed in the unit because of potential electrical hazard and to avoid electrical interference to the monitoring system. Wall-mounted sphygmomanometers, ceiling tracks for hanging I.V. solutions, comfortable lounging chair plus additional standard furniture for patients' room are required. Lighting should permit reading in the chair. It is mandatory that the use of electrical applicances be restricted to meet electrical safety requirements.

9.1 Patient ECG monitoring

Telemetry

Telemetry is the preferred form of monitoring, as it permits monitoring of the patient during all activities regardless of location in the ICCU. This requires that there are no areas in the ICCU from which a satisfactory signal cannot be received by the central nursing station. The geographic limitations of telemetry must be thoroughly established for each ICCU and made known to the staff members and patients. In determining the number of telemetry monitors required, it should be remembered that not all patients in the unit are being monitored.

Bedside monitors (hard wire)

It is desirable to have hard wire outlets for several beds to allow ad hoc use of a bedside monitor for the occasional patient in whom telemetry may be unsatisfactory. In new facilities, it is preferable to provide hard wire outlets at every bedside.

At least one or two portable bedside monitors should be available to allow display of the ECG at the bedside without tying up the crash cart.

Central Monitoring (nursing station)

- Slave oscilloscope
- Heart-rate meter with alarm
- Direct writing ECG strip recorder.

NOTE

Central monitoring must be located in the central nursing station of the ICCU where the monitoring information will be directly and immediately available to the staff that will act on it. The arrangement in which the CCU alone receives and interprets ECG monitoring from the ICCU and then verbally communicates the information to the ICCU staff has been generally found to be unsatisfactory.

With the possible exception of holter-type ambulatory monitoring, it is desirable that ECG monitoring, for all patients with acute myocardial infarctions, be discontinued at least 24 hours and preferably 48 hours before discharge. This policy is intended to allow the patient to regain confidence in his/her ability to be safely active without monitoring. This is an essential part of the rehabilitation process.

9.2 Resuscitation equipment

A complete emergency crash cart must be immediately available to the ICCU. An ECG monitor and D C defibrillator (preferably with synchronizer circuit) must be on the cart. Because of potential use in areas other than patients' rooms, oxygen and suction must be included. The emergency crash cart should also include an adequate supply of drugs and emergency equipment (tracheostomy set, endotracheal tubes, laryngoscopes, airways, manual breathing bag and mask, cutdown sets, disposable syringes and needles).

Every bed should be equipped with bed boards, piped-in oxygen and equipment for oxygen administration, suction equipment and suction outlets.

9.3 Supportive equipment

12 lead ECG

Infusion pump(s) for intravenous drug administration.

10. RELATIONSHIP WITH OTHER DEPARTMENTS AND SERVICES

The ICCU should be located in close geographic proximity or adjacent to the CCU to facilitate transfer of patients and to enhance the continuity of patient-care, flexibility of staffing coverage, augmentation of skills and in-service education.

CARDIAC PACEMAKER UNITS

PREAMBLE

A program for the implantation of permanent cardiac pacemakers requires careful patient selection, choice of an appropriate pacemaker system from an adequate inventory, competent implantation of that system under strict aseptic conditions, careful surveillance (monitoring and observation) before and after implantation, and adequate long-term follow-up of patient after discharge from hospital.

The difficulties in meeting the above requirements have increased with expanding indications for cardiac pacing and with increasingly sophisticated innovations in pacemaker technology.

The pacemaker unit, as described in these guidelines, provides the best means for meeting current and projected requirements, with the lowest morbidity and in the most cost-effective manner.

All major decisions regarding proposed or existing cardiac pacemaker units should be made in the context of community needs and resources.

A cardiac pacemaker unit is defined as a hospital-based clinical unit that is organized, staffed and equipped to provide all services required for pacemaker implantation and patient's follow-up.

A cardiac pacemaker unit requires:

- the shared use of equipment and space with other departments and services, such as the operating room, the cardiac care unit and the intensive care unit;

- the designated use of equipment and space, e.g. office and storage space.

Because of this heavy dependence on shared facilities and the fact that few, if any, members of the staff are involved solely in cardiac pacemaking, the word "unit", when applied to pacemaking, does not necessarily refer to a designated geographic area.

GUIDELINES

1. PATIENT-LOAD

It is evident that a minimum case-load is required to:

- justify the involvement of staff;
- maintain an adequate number of appropriate types of pacemaker and related equipment;
- develop and maintain the skills and competence of the pacemaker team.

1.1 Minimum case-load: The minimum average case-load for a cardiac pacemaker unit should be approximately 25 new implants per year.

It is recognized that this case-load may not be met during the first year or two of operation of the unit, but the assessment of need should indicate that a minimum case-load can be met within a reasonable period of time.

An annual case-load less than 25 implants a year may be acceptable in remote geographic areas. However, acceptability may depend on the ability of the unit to meet the remainder of the guidelines.

In terms of the best use of resources, it is recommended that where a second unit is being considered for a given geographic area, the second unit should not be developed until the first unit is performing at least 150 new implants per year.

1.2 Maximum case-load: No maximum annual case-load can be set at this time.

2. BED REQUIREMENTS

Patients admitted for pacemaker surgery require monitoring and specialized nursing care before and after surgery. Whether these are provided in the cardiac

care unit (CCU), intensive care unit (ICU) or intermediate cardiac care unit (ICCU) will depend on patients' requirements and the degree to which these facilities are available and can meet the requirements described in these guidelines.

The number of monitored beds required is determined by:

(i) caseload;

(ii) average length of uncomplicated post-operative stay:

- for a new implant: three to five days following implantation.

- for pulse-generator replacement: if not performed on a day-surgery basis, approximately 24 hours following implantation.

3. RECOMMENDED DISTRIBUTION OF UNITS

3.1 Types of Units

The activities of a cardiac pacemaker unit may include implantation, pulse-generator replacement and maintenance procedures, patient follow-up, teaching, research and validation of new products. Based on these activities, all units fall into one of two categories, for which the terms Type I and Type II are useful designations.

A TYPE I UNIT provides pacemaker surgery and patient follow-up services, with additional emphasis on clinical teaching, research and validation of new products.

A TYPE II UNIT provides primarily pacemaker surgery and patient follow-up services. This unit should not be implanting DDD (Dual Chamber) pacemakers and also should not be involved with pacemakers for tachyarrhythmias which require extensive

clinical and electrophysiological studies at the specially equipped Type I pacing centres.

The guidelines, unless otherwise specified, refer to both types of unit.

3.2 Distribution of Units

Type I units are usually university affiliated.

Type II units may be developed where indicated by patient-load, resources and geographic location.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Clinical direction

A clinical director should be appointed by the board of trustees and should be a certified cardiologist, internist or a surgeon with special training in cardiac pacing. At least one additional physician should be designated to share constant coverage for daily rounds and emergency calls.

4.2 Policies and Procedures

Policies and procedures should be clearly defined in writing and should include statements concerning admission, monitoring, management, discharge and follow-up of patients. They should include a statement regarding the contents of the pacemaker function records for each patient, a copy of which will be kept in the pacemaker clinic for ready access.

4.3 Responsibilities of staff

Medical

The clinical director will coordinate the activities of the pacemaker team.

Nursing

There should be written policies delegating authority where immediate consultation by the clinical director or the designated assistant(s) is not possible.

There should be written policies authorizing nursing personnel to perform certain procedures which have been approved for delegation of the board of trustees on the recommendation of the medical advisory committee.

Other Staff

The duties and responsibilities of all other staff should also be clearly defined in writing.

5. STAFF ESTABLISHMENT AND COVERAGE

5.1 Pacemaker team

A pacemaker team is essential to provide expertise in:

- mechanical and engineering aspect of pacemaker technology;
- pacemaker electrophysiology;
- relevant surgical techniques;
- temporary and permanent transvenous pacemaker techniques;
- special use of radiological equipment;
- management of complications and emergencies during/after implantation;
- follow-up of patients after discharge.

The composition of the pacemaker team may vary from one unit to another, but generally consists of:

- surgeon (cardiovascular, thoracic or general);
- cardiologist (or internist);
- anesthetist;
- registered nurse;
- radiological technologist;
- biomedial engineering technologist;
- secretary;
- specially trained technician.

In addition to the physician performing the operation, there should be, in the procedure room during every implantation, at least one other professional, such as a nurse or a technician, trained in the management of complications and cardiac emergencies.

The role of individual team members may be affected by staff resources. One individual may serve more than one role.

5.2 Medical staff

The composition of the pacemaker team may vary from one unit to another but generally should include:

- clinical director of unit;
- at least one designated assistant for delegation of responsibility during emergencies;
- attending staff;
- resident staff, if available.

24 hour/seven-day-a-week, on-call coverage is required.

5.3 Nursing staff

There should be nursing staff available in the OR and CCU (or ICU), trained to meet the unique requirements of pacemaker patients.

5.4 Other staff

One member of the pacemaker team should be designated to coordinate stock control, telephone monitoring, communication with and education of patients, and other assigned tasks.

The services of a biomedical engineering technologist should be available for consultation and for maintenance and repair of electromedical equipment.

The services of additional staff may be required to carry out patient follow-up. This work could be done by a registered nurse or by a secretary or technician trained to undertake these duties.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

Medical Staff

The physician performing permanent pacemaker implantation should have had adequate training in a program, where, under supervision, he has performed such procedures. Minimal experience should include at least 20 new implants, and an equal number of replacements under supervisory physician's guidance. This training may be obtained either by association with a Type I unit or by on-the-job training under the guidance of a physician experienced in pacemaker implantation.

Nursing staff

(i) Operative phase:

A registered nurse is required who has special operating room training to supervise the operating room and/or to assist with the procedure. This nurse should have knowledge of pacemaker operative techniques and a working understanding of the specialized equipment, supplies and devices required for the procedures.

(ii) Post-operative intensive care:

Registered nurses are required who have additional training in the unique requirements of pacemaker patients.

(iii) Intermediate care:

Registered nurses are required who have had additional training in the unique requirements of pacemaker patients.

Other staff

A registered nurse or a specially trained technician, capable of managing the pacemaker program, dealing with stock control, telephone monitoring and provision of ongoing communication between patients and staff is essential for operation of the follow-up program.

6.2 Continuing education

Medical staff

Continuing education is required in all relevant aspects of cardiac pacing. It should be physician-organized, even when involving the assistance of private companies.

Nursing staff

In-service education in the relevant aspects of cardiac pacing on a continuing basis is necessary for nursing personnel.

Other staff

Continual updating of related technical skills is necessary.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

7.1 The following supporting departments and services are essential:

- anesthesia;
- biomedical engineering (a readily available, off-site source of consultation will suffice);
- blood bank;
- blood chemistry laboratory;
- ECG laboratory;
- microbiology;
- pharmacy;
- radiology;
- resuscitation team.

7.2 The following are optional:

- cardiac catheterization;
- occupational therapy;
- physiotherapy;

- respiratory therapy;

- social services.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Operating room

Absolute sterile technique is required for pacemaker procedures. All procedures should be carried out in an operating room, rather than in radiology or cardiac catheterization facilities. If this recommendation cannot be met in existing facilities, special techniques must be developed to achieve the mandatory aseptic operating conditions.

8.2 Monitoring facilities

Monitored beds are required whether they be available in the CCU, ICU or in the ICCU.

9. EQUIPMENT

9.1 Pacemaker hardware

9.1.1 The pacemaker team should decide on:

- what pacemaker products are to be used.

- how stock should be controlled.

(Too large an inventory for a particular unit causes confusion in selection and use of equipment inefficiency and increased costs.)

9.1.2 In small units, the products of two or three manufacturers should be sufficient.

9.1.3 The bulk purchasing of pacemakers on a regional or provincial basis is not supported as the clinical disadvantages outweigh potential cost savings.

9.1.4 New pacemaker products should be validated mainly by Type I units.

9.2 Operating room

Required items of equipment for the operating room are:

- ECG monitor, isolated to eliminate electrical hazards and preferably with write-out capabilities;

- mobile fluoroscope with image intensifier, plus lead aprons for all personnel in the operating room;

- resuscitation equipment including defibrillator with sterile external and/or internal paddles;

- equipment for determining pacing thresholds and endocardial signals;

- sterile percutaneous temporary pacing wires.

9.3 Monitored beds (ICU, CCU, ICCU)

The following items of equipment must be immediately available:

- Individual ECG monitors;

- Resuscitation equipment including:

  D.C. defibrillator
  temporary pacing wires
  crash cart
  bed boards
  oxygen and compressed air
  suction
  respirator

- ECG monitor in central nursing station (oscilloscope, heart-rate meter with alarm, direct writing ECG recorder).

NOTE: Attention to electrical safety standards is mandatory, particularly as they relate to patients with temporary pacing wires.

FOLLOW-UP OF PATIENTS WITH IMPLANTED PACEMAKERS

As previously emphasized, the two major functions of a pacemaker unit are implantation and patient follow-up. Most of the previous section applies to both activities. However, in order to cover all the points considered essential, certain specific details regarding patient follow-up are described separately in this section.

Follow-up of patients is a major activity of a pacemaker unit and can be effected by regular scheduled visits by the patient to the physician's office or to a clinic and/or by telephone monitoring.

Pacemaker surveillance is essential for optimal care of all pacemaker patients. The purpose of follow-up is to maintain adequate surveillance of the patient and the implanted pacemaker. It provides for improved patient morale and permits increased pulse-generator longevity, earlier detection of malfunction and decreased morbidity.

1. The type of surveillance chosen depends on local referral patterns, the locale, the preference of both physician and patient, the volume of patients, and the available resources.

2. Facilities required for direct contact with and follow-up of patients are:

   - physician's office; or

   - pacemaker clinic coordinated with or situated in a Type I or Type II unit.

3. Staff establishment and coverage may include:

physician
registered nurse
specially-trained technician
secretary
other members of the pacemaker team, as required.

4. Additional methods used for pacemaker surveillance:

These may include ECG recordings, telemetry recordings, pulse waveform analysis, ambulatory ECG monitoring, telephone monitoring and chest wall stimulation.

4.1 Telephone monitoring can provide for frequent and remote observation without requiring a visit to office or clinic. This is a consideration for the aged and infirm, and for patients living at some distance from the unit. It allows for flexibility of monitoring schedules, and has been found helpful in maintaining pacemaker registries.

4.2 Pulse waveform analysis is a useful but non-essential tool in providing optimum patient care.

4.3 Chest wall stimulation is used in the evaluation of patients with implanted demand pacemakers. Both pacemaker dependency and malfunction of the pacemaker's sensing circuitry can be diagnosed by use of this technique.

5. Programmable pacemaker:

In those institutions using programmable pacemakers, a system of external programming and accurate recording for reprogrammed parameters must be available. At present, the lack of standardization of instrumentation makes this very difficult. This problem can only be resolved by concerted efforts on the part of the manufacturers.

Physicians who are following pacemaker patients should have precise knowledge of individual model specifications and programmable parameters. This is mandatory for interpretation of DDD pacemaker electrocardiograms.

CARDIAC SURGERY

PREAMBLE

Cardiac surgery, and in particular open-heart surgery requiring extracorporeal circulation, is a service that requires the team efforts of highly specialized medical, nursing and allied health personnel, supported by special equipment. The open heart procedures are only a segment of an overall workload of cardiovascular surgery, but place the greatest demands on the skills and resources of the team.

It is expected that the mix of cardiac surgical procedures will change as new developments arise. The majority for the foreseeable future will be for ischemic diseases. Percutaneous Transluminal Coronary Angioplasty (PTCA) is expected to cause less surgery to be done for simple-vessel disease in early cases, delaying the need for bypass surgery for at least several years. Transplants will increase to limits set by the availability of donor organs, while mechanical assist devices (the artificial heart, left-ventricular assist devices) which are now experimental are expected to ultimately become an important part of the treatment of end-stage heart disease.

The guidelines for a viable cardiac surgical unit that follow are based upon currently accepted practice. Future developments may have a significant effect on these guidelines.

Although the special requirements of paediatric cardiac surgical units are not included in these guidelines, much of the information contained in the following guidelines is relevant to these units.

Special circumstances may require exceptions in the application of certain guidelines for cardiac surgery.

GUIDELINES

1. PATIENT-LOAD

The use of population-to-unit ratios as planning guides is not a reliable method of establishing viable cardiac surgical units. Currently recommended ratios range from one unit for every one-half million to one million population and, therefore, serve only as a rough guide. Such a broad range is necessary if variations in disease patterns, population densities and transportation variables are to be considered.

A more useful standard is one based on an average weekly volume of procedures. Recent recommendations for a cardiac-surgery unit call for a minimum patient-load of six heart operations per week requiring extracorporeal circulation. Under certain circumstances, reasonable exceptions to these recommendations may be made. It is assumed that there also will be a certain number of major cardiovascular operations which do not require cardiopulmonary bypass. The recommended minimum patient-load is required to ensure the effective use of personnel and equipment: the workload must be sufficient to develop and maintain the clinical skills and research interests of the staff working in the unit.

2. BED REQUIREMENTS

Bed requirements for a cardiac surgical unit should be considered in terms of levels of post-operative care required:

(a) Post-cardiac surgery intensive care: two to four days. If the post-cardiac surgery intensive care unit is not in close proximity to the surgical suite, it may be necessary for the patient to be cared for in the post-anaesthetic recovery room for four to six hours following surgery.

(b) Intermediate (step-down) care for cardiac surgery patients: about four days. Intermediate care is a level of care that is greater than that provided on a regular nursing unit, and must have facilities for cardiac patient monitoring and a nurse-to-patient ratio sufficient to permit frequent assessment of the patient's condition.

The minimum viable unit would consist of four intensive care beds and four to six intermediate care beds.

The number of beds required for intensive care and intermediate care would depend on the case-load including the number of cardiac operations not requiring extracorporeal circulation.

3. RECOMMENDED DISTRIBUTION OF UNITS

A minimum viable cardiac surgery unit with two cardiovascular surgeons should be capable of providing the needed services for a population of five hundred thousand persons, depending on the established referral patterns.

It is recommended that cardiac surgery units be affiliated with a university's faculty of medicine, as this facilitates the required teaching and research aspects of such a specialized unit.

4. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

4.1 Medical Direction

A cardiac-surgery unit must be under the direction of a cardiovascular surgeon who is actively involved in the performance of cardiac surgical procedures.

4.2 Policies and Procedures

Policies and procedures, as well as other staff orientation material, should be prepared in the form of a manual which should be readily available to all staff of the unit.

Policies should be developed for admission, management and discharge of patients. It is mandatory that a registry for recording results be maintained.

- See also Appendix I, "Guidelines for Policies and Procedures for Special Services in Hospitals".

4.3 Responsibilities of Staff

Policies must be clearly defined regarding the relationships, duties and responsibilities of all members of the unit's medical, nursing and allied health staff.

These should be contained in:

- policies approved by the hospital's governing board and medical advisory committee,
- hospital administrative policies,
- job descriptions for all members of the team,
- organizational charts.

Proper follow-up is an integral part of surgical treatment with special attention paid to pacemaker patients.

5. STAFF ESTABLISHMENT AND COVERAGE

A cardiovascular surgery unit requires 24-hour coverage with adequate staffing at all levels. Qualified medical, surgical, anaesthetic, radiology, nursing and technical personnel should be available for emergency duty at all times.

5.1 Medical Staff

A minimum viable cardiac-surgery unit performing six procedures with cardiopulmonary bypass per week will require two qualified cardiac surgeons. Each cardiovascular surgeon should perform a minimum of 150 cases per year. The remainder of the surgeon's time should be free for research, teaching and consultations, etc. A performance of fewer than two to three procedures per week per surgeon does not provide adequate experience to maintain skills.

5.2 Residents

Various sources state that from four to six surgical residents are required, depending upon the makeup of the medical team. It should be noted that not all residents would be in training as cardiovascular surgeons. Some residents would be rotating through this surgical service.

5.3 Other Medical, Nursing and Allied Health Staff

5.3.1 Operative Phase

During a procedure the following staff are likely to be involved:

Anaesthesia	- 1-2 qualified anaesthesists
Surgery	1 qualified cardiovascular surgeon; - 2 assistants (1 to be a cardiovascular surgeon).
Nursing	- 1-2 scrub nurses; - 1-2 circulating nurses.
Perfusion Team	- 1-2 perfusionists.

Anesthesia for cardiac surgical patients encompasses a variety of special problems. To assure technical competence, frequent changing of the anesthesiologists assigned to cardiac surgery should be avoided.

To ensure a full year of coverage, an institution will require a minimum of two cardiovascular surgeons, five nurses prepared to assist in this procedure and two perfusion technicians. However, perfusion technicians can each cover 200 operations, and the team of five nurses can cover 1000 operations. Staffing for anaesthetic services should be based on one anaesthetist per 150 operations.

5.3.2 Post-operative Phase

- Post-cardiac Surgery Intensive Care:

  Since nursing staffing depends largely on the types of surgery performed and the condition of the patient, no precise guidelines can be established. A nurse-patient ratio of 1:1 is recommended during the first 24 to 48 post-operative hours, with a ratio of 1:2 thereafter.

- Intermediate (Step down) Care

  To provide optimum observation and monitoring, staffing on the basis of a nurse-patient ratio of 1:2 is desirable, depending on the patient's classification.

5.3.3 Clinical Nurse Specialists

A clinical nurse specialist with a master's degree in cardiovascular nursing is required.

5.3.4 Respiratory Therapy, Physiotherapy and Social Work

A respiratory therapist, a physiotherapist and a social worker should be assigned to the unit on a full-or part-time basis, depending upon the average

number of patients. Patients in both intensive care and intermediate care would require these services.

6. STAFF TRAINING AND QUALIFICATIONS

6.1 Initial Qualifications

The complex operating-room environment required by cardiac surgery in terms of equipment and instruments requires constant improvement in technique and proper indoctrination of personnel.

6.1.1 Medical Staff

Surgeons performing cardiac surgery should be certified by the Royal College of Physicians and Surgeons of Canada, Specialty of Thoracic and Cardiovascular Surgery, or equivalent.

Other qualified specialists should have special training and experience in cardiac surgical problems, in addition to the usual certification requirements.

6.1.2 Nursing Staff

- Clinical nurse specialists registered nurses with baccalaureate level qualifications and post-graduate training and experience in cardiovascular nursing.

- Operative Phase

  Registered nurses with operating-room training and experience. Assignment to cardiac surgery of general surgical nurses should be made sufficiently often to develop and maintain the skills required for proper performance in this area.

- Post-Cardiac Surgery Intensive Care

  Registered nurses, preferably with post-basic preparation in intensive care nursing from a recognized educational institution.

- Intermediate (Step down) Care

Registered nurses with knowledge of cardiac arrhythmias.

6.1.3 Perfusionists

It should be recommended that any new perfusionists should have successfully completed a technical course such as that offered by the Toronto Institute of Medical Technology. They should be encouraged to seek certification by the American Society of Extra-corporeal Technology.

6.2 **Continuing**

6.2.1 Medical Staff

Continuing education, attendance at seminars and conferences and carrying out research are essential for the surgeons in such a unit. The research functions must not be removed from the service functions of a cardiac surgery unit.

6.2.2 Nursing Staff

Registered nurses should be encouraged to attend conferences, seminars and workshops, in addition to participating in a continuing in-service educational program. BCLS and ACLS training must be available.

6.2.3 Perfusionists

They must have available sufficient continuing education to maintain their certification.

7. SPECIFIC SUPPORTING DEPARTMENTS AND SERVICES

Cardiology provides the primary support to the cardiac surgery unit, and close cooperation with this service for diagnosis and patient-care is essential.

The following departments and services should be available to the unit:

- Angiocardiography;
- Biomedical engineering (availability of this service from an off-site source will suffice);
- Blood bank;
- Blood gas laboratory;
- Cardiac catheterization;
- Chaplaincy;
- Dietetic services;
- ECG laboratory;
- Haemodialysis;
- Intensive Care Unit;
- Intravenous therapy;
- Laboratory
- Nuclear Medicine;
- Occupational Therapy;
- Non-invasive cardiology diagnostic services;
- Pharmacy;
- Physiotherapy;
- Psychiatry;
- Pulmonary function unit;
- Radiology;
- Respiratory therapy services;
- Social services.

8. SPACE ALLOCATION, UTILIZATION AND SPECIAL DESIGN FEATURES

8.1 Operating Room

The approximate minimum area of the cardiac operating room should total 56 m^2 net. (This size will vary according to requirements in individual circumstances.) A square or rectangular shape has been found to be most efficient. If there is to be a level of activity above the minimum six procedures per week, with extracorporeal circulation, (e.g., eight to ten), at least two fully-equipped cardiac operating rooms will be required.

8.2 Cardiac Surgery Intensive Care

Guidelines established for intensive care and coronary care units should be followed.

Angiographic facilities should be adjacent to both the intensive care area and the surgical area.

8.3 Intermediate Care Level

This unit must be designed to facilitate patient monitoring with the possibility of telemetry and built-in services provided for intensive care beds.

8.4 Support Areas

Storage space in the clean area of the surgical suite for the storage of the extracorporeal pump-oxygenators and other equipment should be provided. This space should also serve as an area in which such equipment may be conditioned and maintained.

9. EQUIPMENT

9.1 Operating Room

- extracorporeal pump-oxygenator;
- additional plumbing for pump heat exchangers;
- adequate supply of hot water;
- doppler, hemocron, cardiac output machine;
- equipment for monitoring electrocardiograph (with provision for three direct pressure measurements);
- facilities for blood gas analysis and pH determinations (not necessarily located in operating room area if results can be made available within required time);
- defibrillator (must always be in the room);

- intra-aortic balloon pump;

- fluoroscopic equipment for insertion of pacemaker, etc.

9.2 Cardiac Surgery Intensive Care

- per equipment required for an intensive care or cardiac care unit.

9.3 Intermeditate Level Care

- facilities for electrocardiographic monitoring

- cardiac massage equipment for closed and open chest, and a defibrillator must be on hand

- equipment usually required for this level of care.

10. RELATIONSHIP TO OTHER DEPARTMENTS AND SERVICES

- The operating room may be part of the general surgical unit where it can share common surgical support systems.

- It is desirable that the operating room be close to angiographic facilities and to the cardiac care unit.

- Post-cardiac surgery intensive care area would be ideally located as close as possible to the surgical suite, and should be adjacent to, but separate from, a general intensive care area.

- Patients at the intermediate care level should be grouped to enable the efficient utilization of personnel and equipment. This unit should be located in relatively close proximity to the intensive care area.

- Complete diagnostic facilities should be geographically associated with a cardiac surgery unit.

IV CARDIAC REHABILITATION

IV CARDIAC REHABILITATION

1. PREAMBLE

The aim of cardiac rehabilitation is to assist an individual in achieving and maintaining his/her physical, mental, vocational and social potential. This is accomplished by an interdisciplinary team effort in conjunction with a supervised exercise program. The inter-disciplinary team should include cardiovascular nursing, social work, psychology, and psychiatry to assist patients experiencing family difficulties, depression or excessive anxiety. The individual's family is viewed as an integral component and should be involved as much as possible.

The concept of secondary prevention is incorporated in a cardiac rehabilitation program. Secondary prevention is the attempt to retard the disease process through the modification of certain risk factors. Univariate trials have largely been unsuccessful. Thus as part of any cardiac rehabilitation evaluation, a full risk-factor profile should be obtained.

2. PATIENT-LOAD

Post-myocardial and aortocoronary artery-bypass-graft patients, as well as those suffering from angina are most suitable for cardiac rehabilitation. In addition, patients with pacemakers, post-operative valvular disease or congenital disease and cardiac transplants may benefit from a graded exercise program.

Patients experiencing psychosocial difficulties in which the cardiac condition is a contributing factor (e.g. mild depression, anxiety) would benefit from such programs. Patients having difficulty due to inappropriate high levels of exertion, anxiety regarding activity levels or early "cardiac cripples" are appropriate. Individuals requiring help with modification of one or more risk-factors would benefit.

3. COMPONENTS OF A CARDIAC REHABILITATION PROGRAM

The various components of a program will depend on the local environment and services.

3.1 Exercise/Mobilisation

(a) In-patient Program (Phase I)

When the patient is stable either in CCU or after surgery, low-level activities are commenced. During the remainder of the hospitalization the intensity of the exercises is gradually increased. These exercises are accompanied by progressive activities of daily living which have equivalent energy requirements. Upon discharge a patient should be able to walk at a pace of 3 mph and ascend and descend a flight of stairs. (See Supplement II)

(b) Out-patient and Maintenance Program (Phase II)

During this time the emphasis is on extending the duration of light to moderate activities. This usually involves walking between 17 and 20 minutes per mile and building up to two miles daily.

The location for such a program is dependent upon the facilities available. The ideal situation is a rehabilitation centre or a hospital rehabilitation department large enough to maintain a separate and distinct atmosphere. Affiliation with a rehabilitation department can be advantageous, especially for patients with musculo-skeletal problems or those with complicating neurological diagnoses e.g. CVA.

(c) Low-Intensity Program

Individuals with a moderate to marked impairment of ventricular function should participate in a low-intensity exercise program. The involvement in a formalized program can assist with their adaptation

to their disease and help alleviate their depression. These patients are at high risk and should be monitored.

3.2 Education

The goal of the educational program is to increase the knowledge and awareness of the cardiac rehabilitation participants and their families about heart disease.

This helps them to cope with their heart problem and to assume responsibility for the modification of their lifestyle.

Education during the hospital phase is designed to acquaint the patient and family with information to help reduce anxiety. It should be recognized that although lifestyle modification information can be introduced, only a certain percentage is retained. Educational materials should be available on heart disease, exercise, safety and benefits.

In Phase II and III, educational events can provide a further knowledge base, help with lifestyle modification changes, and increase the client's ability to assume increasing responsibility for his rehabilitation.

3.3 Support Groups

Formal or informal support groups help spouses cope with the physical, social and psychosocial changes which may have occurred since the onset of cardiac problems.

3.4 Vocational

Vocational counselling and evaluation is an important aspect of any cardiac rehabilitation program. A number of patients fail to return to work due to psychosocial and not physical reasons.

Centres that are involved in vocational training and counselling should be encouraged to develop expertise to deal with the special needs of the cardiac patient. Components of vocational rehabilitation include work histories, job analyses, work simulation techniques, and training for other jobs.

3.5 Risk-factor Modification

(a) Smoking - smoking cessation should be a major goal in any cardiac rehabilitation program.

(b) Hypertension - frequent monitoring of blood pressure should be done.

(c) Obesity - weight control programs should be available.

(d) Other risk-factors should be considered as necessary.

4. Contraindications

There may be absolute contraindications to a standard exercise program. However, modified exercise programs may be possible for some patients excluded from regular exercise programs.

5. Other Complications

A variety of complications might arise out of exercise programs, some of which may be outside of the cardiovascular system. These must be considered in program planning and management of patients.

GUIDELINES

1. PATIENT-LOAD

The number of potential patients can be estimated from a feasibility study. Small, free-standing programs need a minimum of 20-30 patients to justify

the utilization of space and staff. Larger regional centres should have at least 200 patients on the program at any one time to justify a multi-disciplinary team.

2. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROL

2.1 Program Establishment

It should be realized at the outset that each program has specific needs particular to that community. As well, various components of the program may be dependent on the availability of staff. In developing a program an advisory committee should be established. This committee should have representation from cardiology, cardiovascular surgery, cardiac rehabilitation, exercise-physiology leaders, and possibly local community leaders. An initial feasibility study can be performed with the physicians in the community to determine the level of interest and need for such a program. The philosophy of the program should be established and incorporated into a manual of policy and procedures. An internal action committee is also required to implement various stages of the program.

2.2 Referral Procedure

All referrals for cardiac rehabilitation should be physician-initiated. This is important since the primary physician maintains an integral role in the whole rehabilitation procedure.

2.3 Use of Exercise Stress Tests

An exercise stress test (see also guidelines for cardiac stress testing laboratories on page 15) should be carried out 8-12 weeks following discharge from the hospital.

2.4 Prescription of Endurance Programs

Exercise prescriptions should be experienced in terms of type of activity intensity, duration and frequency. (See Supplement I)

2.5 Database

A complete medical and psycho-social database should be obtained.

2.6 Emergency Procedures

A well-established emergency procedure should be established and be incorporated in the manual of policies and procedures. Mock-arrest drills help to maintain staff's alertness and serve as a reminder that such patients are at higher risk as compared with the general population. The arrest cart with appropriate medications and the difibrillator should be checked regularly. Responsibilities for these actions should be assigned.

3. STAFF ESTABLISHMENT AND QUALIFICATIONS

The cardiac rehabilitation team should be led by a physician who has demonstrated competency and interest in the rehabilitation philosophy, exercise physiology, cardiology and preventive medicine. The physician's enthusiasm and personal involvement in the program on a day-to-day basis is important for patients, cardiac rehabilitation staff and referring physicians.

The rest of the cardiac rehabilitation team may comprise:

1. A cardiovascular nurse(s) with CCU or cardiovascular surgery experience and an interest in educational techniques.

2. Exercise leader (physiotherapist, occupational therapist or exercise physiologist).

3. Social worker.

4. Vocational counsellor.

5. Dietitian.

6. Psychologist.

The ratio of exercise leaders to patients will depend on the phase and the type of patients. For Phase II patients or patients in a low intensity class, the ratio should be 1/5. For maintenance programs with low-risk patients the ratio can be 1/15.

The cardiac exercise classes are likely to be scheduled in either early morning or evening. This requires additional hours of work by staff or the hiring of individuals who work split shifts.

All staff should be currently certified in BCLS. As well they should have had a general course in cardiac rehabilitation. Staff supervising exercise sessions should be familiar with the adverse effects of exercise, be able to interpret exercise electrocardiograms and be currently certified in ACLS.

4. SPECIFIC SUPPORTING SERVICES

(a) Stress-testing facilities

A well established non-invasive laboratory which has stress-testing facilities to perform the graded exercise test.

(b) Resuscitation team or alternate arrangements

If a cardiac rehabilitation program is in a free-standing structure, then the emergency protocol should include the acute cardiac facilities to be used in the event of an emergency.

(c) Laboratory services (biochemistry, haematology)

(d) Audio-visual department

5. SPACE ALLOCATION

Physical facilities include a flat walking/jogging track, a large area for warm-up and stretching exercises, an area for stationary bicycles and a separate area for specialized exercise programs, e.g. upper extremity testing. Appropriate office space with counselling rooms should be available. Smaller rooms appropriate for small group discussions should be available. A larger lecture room with appropriate audio-visual aids for educational events is necessary.

6. EQUIPMENT

- a treadmill
- ECG equipment for 12 lead electrocardiogram
- ambulatory monitoring devices
- resuscitation equipment including oxygen, defibrillator and drugs
- time clocks
- free standing weights
- blood pressure sets
- bicycle ergometers
- upper extremity ergometer or combined arm and leg ergometer

7. RELATIONSHIPS WITH OTHER DEPARTMENTS

It is important to have ongoing input and good relationships with representatives from cardiology, cardiovascular surgery, metabolism, psychiatry, general rehabilitation services.

The philosophy and scope of cardiac rehabilitation is broad and encompasses the medical and psycho-social domain. Active participation by acute care staff on expert committees, steering committees, or educational events completes a fully integrated cardiac rehabilitation program.

SUPPLEMENT I

PRESCRIPTION OF AN ENDURANCE PROGRAM

The exercise prescription should be expressed in terms of four components as follows:

1. **Type of activity** e.g. walking, jogging, swimming, long-distance cycling, cross-country skiing and calisthenics designed for endurance. High risk patients or those with musculoskeletal problems may prefer stationary cycling.

   It should be emphasized that patients with coronary artery disease should not use sports or games to achieve a fit state.

2. **Intensity** - the intensity is derived from the graded exercise test. This should be between 50-70 per cent of the maximum oxygen consumption. The usual exercise prescription is based on 65-80 per cent of the maximum heart rate or 60-75 per cent of the heart rate reserve (maximum heart rate achieved minus resting heart rate). If a patient develops complications at a specific intensity, then this heart rate should not be exceeded during exercise. Complications in programs have often occurred with patients exceeding their training heart rate. The exercising heart rate during the supervised exercise class can be higher than that of the programs at home.

3. **Duration** - exercise should be steady, continuous and last for a minimum of 20 and preferably 30 minutes. The intensity chosen should permit this without excessive fatigue developing. Patients with claudication or effort angina may accomplish more with a discontinous type of program.

4. **Frequency** - two sessions a week is minimal for maintaining a fit state once this has been reached. For training, however, a minimum of

three and preferably four to five sessions weekly are recommended. As the number of sessions exceed five, there is an increased incidence of musculo-skeletal problems. One or two of these weekly sessions should be supervised.

Other Aspects - training sessions should include a warm-up and cool-down, and a flexibility routine should be practised to reduce the incidence of injuries. Patients should be instructed in pulse-taking, recognition and interpretation of symptoms, effect of various medications on exercise tolerance, the effect of different climatic conditions, and the choice of suitable footwear and clothing. Progress should be measured by regular exercise testing, and both telemetry and holter monitoring should be available.

SUPPLEMENT II

BENEFITS OF EXERCISE

1. **Direct benefits**

- improvement in mood and self-confidence, with alleviation of depression;

- reduction in resting and working heart rates and blood pressure, resulting in a reduced myocardial oxygen consumption and an increased threshold for angina;

- an increase in maximum stroke volume, cardiac output and maximum oxygen consumption;

- greater oxygen extraction by trained skeletal muscles as well as reduced vascular peripheral resistance during heavy work;

- increase in plasma HDL cholesterol levels;

- enhanced sensitivity to insulin and improved glucose tolerance;

- reduction in stress-induced secretion of serum catecholamine;

- increased fibrinolytic activity and reduced tendency towards platelet aggregation.

2. **Associated pertinent benefits**

- greater motivation to maintain an ideal body weight;

- increased incentive to stop smoking;

- improved nutritional habits;

- heightened awareness of a healthy lifestyle;

- improved ability to recognize and interpret symptoms and signs;

- closer monitoring of the disease state, with subsequent improvement in prognosis through reinvestigation, changes in drug regimen or possibly more aggressive intervention.

- personal contacts with people with similar problems; mutual support and understanding.

V ADDITIONAL CONSIDERATIONS

V ADDITIONAL CONSIDERATIONS

RESUSCITATION TEAMS

PREAMBLE

A cardiac resuscitation team is an organized group of professionals who respond to the patient whose heart and/or lungs have stopped functioning. The team institutes a series of treatment modalities designed to bring about return of cardiac and/or respiratory function. The team responds to a call for resuscitation of any patient whose spontaneous cardiac and/or respiratory function has ceased.

GUIDELINES

1. PATIENT POPULATION

Any patient who has a cardiac arrest or cardiorespiratory arrest is a potential candidate.

2. ADMINISTRATIVE POLICY, PROCEDURES, AND CONTROL

2.1 Policies

The hospital will have written policies indicating the type of patient to be resuscitated, the procedure to follow if a patient is not to be resuscitated, the members of the team, the type of call system to be used. All team members will be covered by policies to protect them for the measures they are expected to undertake.

2.2 Team Roles

Team Captain

The team captain assesses the patient's cardiac/respiratory status and orders or institutes appropriate treatment measures including drugs, dosages,

venous access lines, intubation, defibrillation and/or cardioversion voltages. The captain should be capable of instituting any of the measures prescribed.

Airway Manager

Obtains and maintains an open airway on the patient. Manages ventilation using appropriate equipment. Must be capable of intubation.

Chest Compressor

Provides effective manual cardiac compressions on the closed chest or attaches and monitors the function of external mechanical chest-compression equipment.

Drug Dispensor

Prepares and administers drugs as ordered by the team captain. When appropriate starts an intravenous infusion using a catheter.

Defibrillator

Administers defibrillation/cardioversion as ordered by the team captain.

Recorder

Keeps a running record of all treatments and procedures carried out during the arrest.

Runner

Brings and sets up equipment and supplies not on the resuscitation cart. Controls traffic and removes excess personnel and/or visitors.

In practice these roles will usually be paired in part, combining either drug dispenser/defibrillator

or team captain/defibrillator and drug dispenser/ recorder, so that the roles can be performed by a group of four or five persons.

3. STAFF COVERAGE

Coverage is provided on a 24-hour basis. Additional team members may be assigned or the duties of other members may be divided among additional personnel, remembering that too many personnel often leads to confusion.

4. STAFF TRAINING AND QUALIFICATIONS

4.1 Initial Qualifications

Team Captain

The team captain is a qualified physician or registered nurse. Initial training should include the status of advanced cardiac life-support provider. Should be capable of initiating intravenous lines, giving intravenous medications, intubation, defibrillation/cardioversion.

Airway Manager

An anesthesist, physician, respiratory technologist or nurse trained in oral and endotracheal intubation and airway management. Advanced cardiac life-support status is required.

Chest Compressor

Person trained in external cardiac massage with certificate in basic cardiac life support. Preferably an intern, resident or nurse.

Drug Dispensor

A nurse with experience in critical care or acute coronary care who is a provider in advanced cardiac life support. Requires special training in

intravenous push medications. The ability to start an intravenous infusion using a catheter is necessary.

Defibrillator

A nurse with experience in critical care or acute coronary care who is a provider of advanced cardiac life-support and has special training in defibrillation and cardioversion.

Recorder

The recorder should be familiar with all treatments and procedures to be required during the arrest to keep the legal record; preferably a registered nurse.

Runner

Any staff member familiar with the possible equipment required during the arrest procedure.

4.2 Continuing Education

All members of the team should be required to go through the resuscitation procedure on a regular basis to keep current on new techniques, drugs and procedures to be used. All members must maintain current certification in basic cardiac life-support and should be updated in advanced cardiac life-support where a provider status is required.

5. EQUIPMENT

All equipment should be portable, and should include:

Portable direct current monitor/defibrillator preferably with heart rate meter, oscilloscope and paper writing capabilities. The ability to synchronize is preferred.

Portable oxygen and suction equipment.

Drugs -- premixed syringes are preferred. Drugs must be reviewed on a semi-annual basis to determine if the drug list should be changed. Intravenous supplies and equipment for cutdown or central line insertions should be included.

Airway management equipment including endotracheal tubes, oral airways, hand ventilators and masks.

An infusion pump or controller should be available.

Blood pressure monitoring equipment should be available.

All equipment should be checked at the beginning of each shift. In addition, a biomedical engineer should check the output of the defibrillator on a regular basis.

INTERFACILITY TRANSFERS[7]

PREAMBLE

Interfacility transfers involve the movement of critically ill patients from one facility to another. The receiving facility provides an intensity of treatment or type of diagnostic investigation which is not available in the original facility. In response to this need, suitably organized teams must be assembled and equipped for the continuous observation, monitoring and treatment of patients during the required transfer. The patients may present with:

1. Acute coronary heart disease

2. High risk arrhythmias

3. Certain types of non-ishchemic heart disease patients transferred due to the presence of risk of complications.

4. Other intensive care cases.

GUIDELINES

1. PATIENT LOAD

All patients requiring transfer from a critical care unit to another facility and/or requiring cardiac monitoring should be included as a part of the patient load.

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[7] This section is to be read in conjunction with the guideline, Prehospital Emergency Services, Subcommittee on Special Services in Hospitals, Health Services Directorate, Department of National Health and Welfare

2. ADMINISTRATIVE POLICY, PROCEDURES AND CONTROLS

2.1 Medical Direction

During the transfer process, the patient will be under the care of the referring doctor unless the receiving facility sends a physician to assume this responsibility. Appropriate orders should be provided to the transfer team for treatment of cardiac and other complications, including resuscitation.

2.2 Policies

Policies should be in writing describing the responsibilities of each member of the transfer team. Included should be statements of the appropriate transfer of function for giving of medications and treatments, including defibrillation and synchronized cardioversion.

2.3 Responsibilities of Staff

Medical

Provide clear, complete written orders for treatment of complications and resuscitation. Attend and accompany the unstable patient requiring complex treatments such as a peri-cardiocentesis needle or catheter. In the event that complications arise en route in the absence of the referring physician, that physician must be immediately available to provide supplementary instructions by radio until such time as the receiving physician assumes responsibility.

Nursing and Emergency Medical Attendants

Provide appropriate treatment measures for the patient including monitoring and functions designated as medical acts but transferred.

3. STAFF COVERAGE

A minimum of one registered nurse, with appropriate policy coverage to diagnose and treat lethal arrhythmias and other complications is required with all monitored patients, plus two emergency medical attendants. The physician will also accompany the patients as noted in 2.3. In some cases a respiratory therapist will be required.

4. STAFF TRAINING AND QUALIFICATIONS

4.1 Initial Qualifications

Medical Staff

The accompanying physician must be aware of the patient's condition and be able to provide written orders for appropriate treatment of complications. That physician should be currently certified in advanced cardiac life-support and should preferably be a specialist in emergency medicine. In certain cases another specialist might be appropriate, if available, according to the patient's condition.

Nursing Staff

The nurse should have at least one year of service in a critical care unit and have managed or served as a part of the resuscitation team. A provider's course in advanced cardiac life-support is required along with current certification in basic cardiac life-support.

Emergency Medical Attendants

Require current certification at least at the EMA I level or its equivalent; certification in advanced cardiac support desirable. Emergency medical attendants with EMA II or higher levels may assume responsibility for transfers at the direction of the attending physician, in lieu of transfer nurses.

4.2 Continuing Education

Medical Staff

Post graduate courses, clinical conferences, and seminars should be attended yearly. Yearly certification in basic cardiac life-support is mandatory.

Nursing Staff

Yearly certification in basic cardiac life-support is mandatory. Seminars, workshops and conferences and in-hospital education programs are encouraged.

Emergency Medical Attendants

They require current certification at the EMAI level and in basic cardiac life-support. Updating seminars, conferences and workshops is encouraged.

5. EQUIPMENT

In addition to the equipment recommended in the guidelines for prehospital emergency services, the referring hospital may be required to provide:

5.1 Portable equipment for direct current monitoring with heart rate meter, oscilloscope, and preferably with direct writing capabilities; direct current defibrillation equipment with the ability to synchronize.

5.2 Portable equipment for blood pressure monitoring or alternately an ultrasonic stethoscope.

5.3 Mechanical ventilation equipment and adjuncts.

5.4 Drugs -- the usual supply of intravenous drugs required for resuscitation including intravenous supplies and solutions. Drugs specific to the patient's problem should also be carried.

5.5 A controller or infusion pump.

Other equipment and drugs may be required, depending on the patient's condition. All equipment should be field tested prior to use on a patient to ensure that it will function properly in a moving ambulance vehicle; this is particularly important if it is contemplated to use it on aircraft.

SAFETY REFERENCES

Electrical

1. Use of electricity in patient care areas Canadian Standards Association STD CAN 3-Z32.2-M81.

2. Essential Electrical Systems for Hospitals Canadian Standards Association STD. Z32.4-M 1978.

3. Electromedical Equipment Canadian Standards Association STD C22.2, No. 125-1979.

The above references may be obtained from:

The Canadian Standards Association,
178 Rexdale Blvd.,
REXDALE, Ontario
M9W 1R3

For Quebec and Atlantic Regions:

The Canadian Standards Association
149 Oneida Drive,
POINTE-CLAIRE, Dorval, Quebec.

Radiation

1. Safety Code Laboratory Facilities for Handling Radioisotopes. Publication of Department of National Health and Welfare: RPD-SC-12, 1974.

The above reference may be obtained from:

Atomic Energy Control Board,
P.O. Box 1046,
OTTAWA, Ontario
K1P 5S9

The following publications are distributed by the Radiation Protection Bureau, and may be obtained from:

Radiation Protection Bureau,
Brookfield Road,
OTTAWA, Ontario
K1A 1C1

2. Acts and Regulations

Radiation Emitting Devices Act (Chapter 34)(1970)

Radiation Emitting Devices Regulations (SOR/72-43)(1972)

Atomic Energy Control Act (Chapter A-19)(1970)

Atomic Energy Control Board Regulations (SOR/74-334)(1974)

3. Safety Codes

RPB-SC-10 Installation and Safety Procedures for the Use of X-Rays in Medical Therapy

RPB-SC-14 Policy Respecting the approval of Applications for the Use of Radionuclides in Humans

RPB-SC-20a Xray Equipment in Medical Diagnosis, Part A: Recommended Safety Procedures for Installation and Use.

RPB-SC-22 Radiation Protection in Dental Practice; Recommended Safety Procedures for Installation and Use of Dental Xray Equipment

RPB-SC-23 Guidelines for the Safe Use of Ultrasound, Part 1: Medical and Biomedical Applications.

GUIDELINES FOR POLICIES AND PROCEDURES FOR SPECIAL SERVICES IN HOSPITALS

Guidelines for policies and procedures for special services in hospitals were formulated after a review of provincial, national and international information.

It is hoped that the following outline will serve as a guide for the development of policies which are more comprehensive and for specific special services to ensure the most effective and efficient delivery of patient care in these units.

I. ROLE AND OBJECTIVES

- Philosophy role and objectives of the service
- Type of patients served
  - By diagnosis and/or severity of illness
  - Restriction of service, if any
- Services provided

II. ORGANIZATION OF SERVICE

- Responsibility of Governing Board
- Relationship to administrator and medical staff
- Service management

1. Specific responsibilities of staff
   - Medical director
   - Other medical staff

- Nursing staff
- Other staff

2. Committees

- Membership to be defined by discipline and number
- Terms of reference to be defined
- Provision for consultation with appropriate hospital and medical staff
- Schedules for formal and ad hoc meetings

III. POLICIES FOR OPERATION OF SERVICE

1. General

- Admission authority (Identification of individual(s) who have authority to admit)
- Admission priorities by:
  - Diagnostic category
  - Clinical condition
  - Routine admission standing orders
  - Medical orders
  - Emergency admission standing orders
  - Length of stay by diagnosis
  - Infection control and isolation
  - Patient records, reports and charting
  - Handling of emergency situations including C.P.R.

- Emergency delegation of responsibility to medical, nursing and/or other staff
- Research/clinical investigation
- Palliative care, determination of death, authorization for autopsies, handling of bodies
- Referral, consultation (mandatory and other transfer, follow-up)

2. Staff

- Selection criteria: education, experience, interests
- Criteria for granting medical/clinical privileges
- Medical coverage/staff coverage of service
- Delineation of student's and supervisor's roles including responsibility, authority and accountability
- Position descriptions
- Orientation and continuing education
- Performance evaluation
- Volunteers

3. Patient

- Patients' rights
- Patients' identification
- Family participation
- Confidentiality

- Patient/family education
- Patients' valuables, assets and belongings
- Consent for treatment
- Visiting privileges

4. Safety

- Safety and accident prevention
- Reporting of accidents and incidents
- Equipment maintenance and safety
- Fire and disaster plan
- Use of restraints

5. Quality Assurance

- Practice standards
- Continuing evaluation of effectiveness of service
- Patients' status-assessment on admission and discharge
- Incident reports
- Patient-care review
- Infection control
- Audits: medical and nursing care, concurrent and retrospective
- Peer review
- Morbidity/mortality review
- Employee performance appraisal

- Product and equipment use and evaluation

IV. PROCEDURES

- Elective procedures
- Emergency alert system procedures
- Medical record and statistical procedures
- Policy and procedure manuals

APPENDIX II

GUIDELINES FOR SPECIAL SERVICES IN HOSPITALS

The following guidelines have been prepared by the federal-provincial Sub-committee on Institutional Program Guidelines. These guidelines were requested by the Federal-Provincial Advisory Committee on Institutional and Medical Care Services. Some of the guidelines are updated versions of guidelines previously published by the Sub-committee.

Addiction Services
Adult Psychiatric Services Provided by General Hospitals
Adult Long Term Institutional Care
Burn Unit
Cardiovascular Services in Hospitals
Child and Adolescent Psychiatric Services Provided by General Hospitals
Child and Adolescent Services in General Hospitals
Child and Youth Long Term Services
Computed Tomography
Day Medicine
Day Surgery Unit
Dental Care Units in Hospitals
Diabetic Day Care Unit
Diagnostic Imaging Services and Systems, An Overview
Diagnostic Ultrasound Facilities in Hospitals
Emergency Services in Hospitals
Geriatric Day Hospitals
Geriatric Unit in a Hospital
Intensive Care Unit
Nuclear Medicine in Hospitals
Palliative Care Services in Hospitals
Patient Hostel Unit
Perinatal Intensive Care Unit
Pulmonary Function Laboratories
Regional Renal Failure Program
Rehabilitation Medicine Unit

Respiratory Technology Service/Unit
Reuse of Disposables: An Information Report
Spinal Cord Injury Unit
Stroke Services